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14. ABSTRACT

The goal of the funded work was to establish the NRH Neuroscience Research Center (NRC) whose mission is to promote and accomplish rehabilitation-related basic and applied neuroscience research. Funding supported the development of research studies in the areas of neurobehavioral and neuromotor assessment, traumatic brain and spinal cord injury, stroke, and Parkinson's disease. Research supported by the USAMRMC occurred in five research areas. They are as follows: a) High Resolution and Neuromotor Assessment; b) Mechanisms Underlying Recovery from Neurological Illness and Injury; c) Treatment of Neurological Diseases and Injury; d) Pilot Projects; and e) Annual Conference and Expert Panel Projects. Funding supported agenda-setting conferences in stroke rehabilitation and neuroprotection. Funding also supported the building of selected infrastructure including space and research databases. One clinician researcher obtained NIH training funds and a second has applied.

15. SUBJECT TERMS
Neuroscience, rehabilitation, traumatic brain injury, spinal cord injury, stroke, Parkinson's disease

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INTRODUCTION

The NRH Neuroscience Research Center (NRC) grant has enabled the National Rehabilitation Hospital (NRH) to create the infrastructure to support core elements associated with the development of a true Neuroscience Research Center. These elements include new staffing; collaborating with other organizations; developing related projects; facilities construction; supporting pilot projects; and the NRC Guest Lecture series.

Active Collaborations with other organizations:

- National Institutes of Health (NIH)
- Uniformed Services University Health Sciences (USUHS)
- Georgetown University Medical Center/GUH
- Catholic University of America
- The Washington DC Veteran's Affairs Medical Center
- National Institute on Disability and Rehabilitation Research (NIDRR)
- The Miami Project
- The Rehabilitation Institute of Chicago (RIC)
- University Maryland
- Children's National Medical Center
- Emory University
- University of Southern California
- Johns Hopkins University
- University of Wisconsin
- University of Maryland

Developing related projects

Currently performing:

- NIDRR- National Capital Spinal Cord Injury Model System
- NIDRR- Rehabilitation Research and Training Center for Spinal Cord Injury
- NIH-
    - Transcranial Direct Current Stimulation study in individuals with stroke.
    - National Capital Area Rehabilitation Research Networks
    - Stroke Disparities Program 1 U54 NS057405-01 (C. Kidwell, PI)
    - Interdisciplinary Comprehensive Arm Recovery Evaluation Stroke Initiative (I-CARE) 1U01NS056256-01A2
- NIH Training Grants
    - Dr. Timea Hodics MD—Funded 2007 1 K23 HD050267
    - Dr. Michelle Harris-Love PT PhD--applied

Facilities Construction

The effort to create a geographically defined Neuroscience Research Center at NRH devoted to rehabilitation-related neuroscience research has made major accomplishments :

1. *Modification and expansion of the originally proposed 2-stage physical space plan.* After careful thought with both a commissioned architect and the hospital administration, it was decided to modify the originally proposed 2-stage space plan by expanding it from 2,000 square feet on each floor for a total of approximately 4,000 square feet for a total of approximately 5,000 square feet on one floor. This allowed the consolidation of most of the research activities into one contiguous and concentrated area. Approximately 2,200 square feet of the new 5,000 square feet was devoted to neuroscience research. This was in addition to the approximately 1,000 square feet current occupied by the neuroscience research center staff. The new physical space for the Neuroscience Research Center is indicated in Figure 1 below.

Figure 1. Neuroscience Research Center / Research Division physical space layout.

2. *Obtained the capital funds for the construction of the new physical space.* NRH had over for construction and renovation of the new physical space, which did not include the construction funds budgeted in the current cooperative agreement.
3. *Completion of the construction plans for the new physical space.* Through the efforts of the commissioned architect and NRH administration, the construction plans for the new physical space were completed and submitted to the DC government, approved and construction completed.

Development of the NRC Research Capacity

With these new infrastructure pieces collaboratively developed, the neuroscience research community at NRH has developed considerably. The focus has been on areas important to health care in general, but also on aspects of neuroscience relevant to the

needs of service men and women and their families. This multidisciplinary group includes neurologists, physiatrists, physical occupational and speech therapists, biomedical engineers, economists, consumers, and statisticians. Funding has been obtained from the National Institutes of Health, NIDRR, the Veterans Administration, and other sources. Almost all of the funded work has direct relevance to the needs of service men and women or their families. Many of these projects underwent development as a direct or indirect result of the NRC.

Accomplishment of Research Goals

Four specific themes were outlined in the original proposal:

1. High resolution neurobehavioral and neuromotor assessment
2. Mechanisms underling recovery from neurological illness and injury
3. Treatment of neurologic disease and injury
4. Pilot studies

The remainder of this report will describe the research projects and their results, each of which addresses one or more of the above themes.

BODY

Project A1: A Computerized Neuropsychological Battery for Parkinson's Disease: Application for Population Surveillance, Early Detection, and Monitoring Disease Progression

Parkinson's disease (PD) is a neurodegenerative disorder that presents with a specific set of motor symptoms, including tremor, rigidity and bradykinesia. PD also typically affects cognition and mood similar to that observed in other subcortical neurodegenerative diseases. Approximately 1% of the population over age 50 suffers from PD. Although 40% of patients with PD are between the ages of 50 and 60, there is evidence the "early-onset" PD is on the rise, with an estimated 10% of recently diagnosed patients under age 40. Current therapies for PD focus on amelioration of PD symptoms and slowing disease progression. Future therapies, however, will focus on arresting and even reversing the disease process. Since substantial neuropathologic change, as indicated by greater than 60% loss of dopaminergic neurons, typically precedes manifestation of clinical symptoms in PD, future therapies likely will create a compelling need for early identification in order to permit initiation of treatment prior to the occurrence of extensive CNS insult. The early loss of dopaminergic neurons in PD suggests that subtle neurocognitive changes and subclinical motor symptoms may be seen early in the disorder, possibly before the onset of symptoms necessary for a clinical diagnosis. A test battery sensitive to subtle cognitive dysfunction and subclinical motor symptoms would aid in early detection of PD and monitoring of disease progression. The DoD-developed Automated Neuropsychological Assessment Metrics (ANAM) provides a well-developed starting point. Sensitivity of this measure to cognitive change has been demonstrated in sports concussion, fatigue, exposure to altitude, systemic illness, and pain secondary to headache.

The primary objective of the study was to develop an effective and highly efficient computerized testing system for population surveillance, early identification, and clinical monitoring in PD, using ANAM as the cognitive component. PD symptom specific measures of mood and motor functioning will be added to the current ANAM test battery. Special emphasis was placed on measures that target the earliest subclinical symptoms of PD that would normally go undetected in the typical neurological exam. Not only did this new ANAM battery the first of its kind to focus on subtle cognitive change in neurodegenerative disease, it continued to be both cost- and time-efficient and able to be universally administered using a simple computer and mouse interface.

The primary progress was the identification of settings and patient populations to be used for validating the procedures and instruments developed in this proposal. This has included incorporating Parkinson's disease and movement disorders clinical programs which simply were nonexistent at the time the original proposal was written. For example, as described in greater detail below, the Washington Hospital Center recently has developed clinical programs for Parkinson's disease and movement disorders, including deep brain stimulation and other advanced services, and two of the physicians directing these services, Drs. Lin and Levine, have joined this project as investigators.

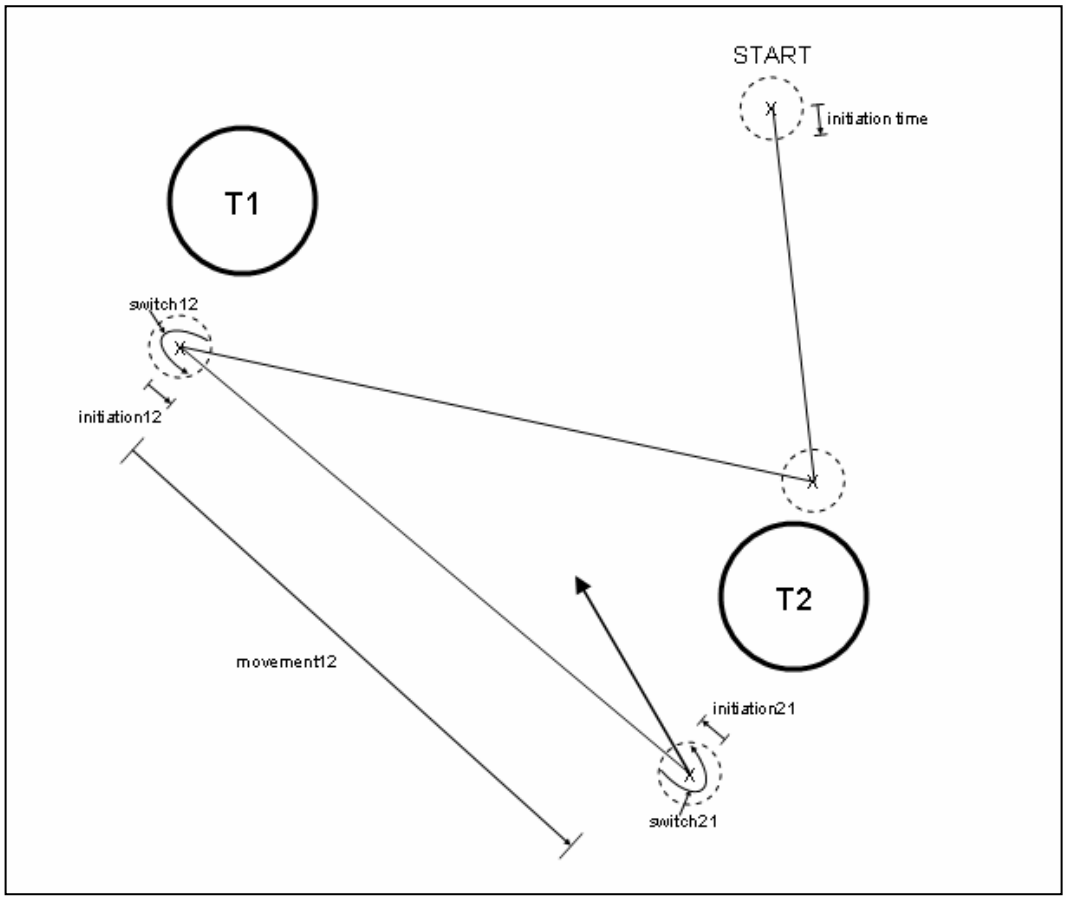
The following elements of the originally proposed motor tasks were completed. First, a "shell" providing a common foundation and infrastructure for the motor tasks has been designed and created. This shell is cosmetically similar to the existing ANAM shell and is designed so that the user (subject or patient) experiences continuity when moving from the existing ANAM cognitive tasks to the presently developed motor tasks. While these tasks can be integrated within the current ANAM shell using the "alias" feature of the .lst file, these tasks will be submitted to Kathy Winter, SPAWAR, to optimize integration within existing ANAM technology.

An overall strategy and architecture for motor task development was developed in order to maximize compatibility across newly developed tests and facilitate future modifications. Consistent with ANAM philosophy, the motor test development strategy emphasizes flexibility for the examiner to modify test parameters and to select and aggregate specific motor tests into "batteries." Following development of the framework, the first motor task was prototyped. This task, the Alternating Two-point Target Acquisition subtest (ATPTA) has been completed.

tblATPTA : Table

Field Name	Description
SubjID	subject ID
Dat	date of the subtest
Tim	time of the subtest
ATPTAtrialnum	trial number
ATPTAtimInit	initiation time
ATPTAtimInitAvg12	average initiation time moving from Target1 -> Target2
ATPTAtimInitAvg21	average initiation time moving from Target2 -> Target1
ATPTAtimInitAvgTot	total average initiation time
ATPTAtimSwitchAvg12	average switch time moving from Target1 -> Target2
ATPTAtimSwitchAvg21	average switch time moving from Target2 -> Target1
ATPTAtimSwitchAvgTot	total average switch time
ATPTAtimMvmtAvg12	average movement time moving from Target1 -> Target2
ATPTAtimMvmtAvg21	average movement time moving from Target2 -> Target1
ATPTAtimMvmtAvgTot	total average movement time
ATPTAclickMean	average time between clicks
ATPTAclickSD	std dev of click times
ATPTAnumClicks1	number of clicks attempting Target1
ATPTAnumClicks2	number of clicks attempting Target2
ATPTAnumClicksTot	total number of clicks attempting either Target
ATPTAnumCorr1	number of clicks INSIDE Target1
ATPTAnumCorr2	number of clicks INSIDE Target2
ATPTAnumCorrTot	number of clicks INSIDE either Target
ATPTAnumIncorr1	number of clicks OUTSIDE Target1
ATPTAnumIncorr2	number of clicks OUTSIDE Target2
ATPTAnumIncorrTot	number of clicks OUTSIDE either Target
ATPTApctCorr1	percent of clicks INSIDE Target1 when aiming for Target1
ATPTApctCorr2	percent of clicks INSIDE Target2 when aiming for Target2
ATPTApctCorrTot	percent of clicks INSIDE either Target
ATPTApctIncorr1	percent of clicks OUTSIDE Target1
ATPTApctIncorr2	percent of clicks OUTSIDE Target2
ATPTApctIncorrTot	percent of clicks OUTSIDE either Target
ATPTAavgIncorrDist1	average distance (percent radial) of incorrect responses to Target1
ATPTAavgIncorrDist2	average distance (percent radial) of incorrect responses to Target2
ATPTAavgIncorrDistTot	average distance (percent radial) of total incorrect responses
ATPTAnumFreeze1	number of freezes on Target 1
ATPTAnumFreeze2	number of freezes on Target 2
ATPTAnumFreezeTot	total number of freezes
ATPTAaccel	acceleration
ATPTAtremor	tremor

Another element of test design strategy and architecture has focused on data structure and design, and automation of transfer of test data from data files to databases. Tests are designed using three programming logic groups, or "layers": user interface logic, business logic, and data logic. This was done so that future changes, whether they be in test parameters, operating systems, data management systems, etc., would not require complete redesign of the test, but only redesign of the specific logic section. We also have completed design and programming of preliminary templates for each logic section. These templates specify code requirements for new subtests, such that the additional motor tasks in our proposal already have a code "template" to assure that they will integrate seamlessly into our framework, as well as to provide a development map to expedite and increase the efficiency with which the additional tests will be developed. Moreover, since motor tasks can yield a nearly infinite number of test "scores," we have identified a set of preliminary output variables, listed below:



In addition to task development, progress was made regarding developing several approaches to validating the tests. A test validation protocol was written and approved by the Medstar IRB. The protocol emphasizes demonstration of test sensitivity to the symptoms of Parkinson's disease using pre-and post-treatment symptom comparisons, both following pharmacologic and deep-brain magnetic stimulation. Specifics of study design and subject recruitment have been finalized with our new collaborators at the Washington Hospital Center, Drs. Mark Lin and Zachary Levine. In addition to

assessing the efficacy of the newly developed motor tasks, the protocol included the cognitive and affective symptoms common to Parkinson's disease.

Report pilot data was collected on 40 subjects, and 13 of those subjects served as age, education, and gender-matched controls. Currently, pilot data has been collected on 71 subjects, and 20 of those subjects serve as age, education, and gender-matched controls. All of the 51 subjects with Parkinson's disease have been tested at least once and can be used in the cross-sectional arm of the study. Of these 51 subjects, 24 have been tested two or more times, on or off medication, and 11 have been tested pre-and post deep brain stimulation surgery.

Two databases were developed. The first has been within COMPASS in order to store of the voluminous data generated by the computerized tests within the battery and facilitate creation of summary scores used for clinical and research interpretation of the results of each subtest within the COMPASS battery. The second database included subject demographics, their status with respect to disease parameters, medication and surgical status, and other variables useful for describing each subject. This second database is used for data analysis and generation of publishable data.

Project B1: The Impact of Self-Awareness on Functional Outcomes Following Moderate and Severe Traumatic Brain Injury

The purpose of this study was to examine the relationship of self-awareness following traumatic brain injury (TBI) to functional outcome six months after inpatient rehabilitation. It was hypothesized that self-awareness was a salient variable affecting functional outcome. The study represented one of a series of follow-up studies designed to gain further understanding of self-awareness deficits following brain injury.

Project B2: Gait Restoration in Stroke and Incomplete SCI Patients Using the Lokomat Robotic Treadmill System

The primary objectives of this study were two fold. For the stroke leg of the study, our goal was to determine whether robotic-assisted gait training using the Lokomat (Hocoma AG, Volketswil Switzerland) improved walking capabilities to a greater extent than conventional gait training in sub-acute, hemiparetic stroke survivors. Here, 50 individuals were tested at NRH, randomly assigned to either the Lokomat or conventional group. Each subject received 24, 1 hour training sessions over a 10-week period. Outcomes were measured at weeks 0, 4, 8, and 20, and included over-ground walking speed, 6-minute walk test (endurance), Ashworth (spasticity) and quality of life measures. We hypothesized that because the Lokomat would deliver more intensive, consistent gait training, overall walking ability and lower extremity motor function would improve more in the robot group than in the conventional trained subjects.

In the SCI portion of the study, our primary objective of this project was to determine whether long-term robotic-assisted locomotor training improves the overall health and quality

of life of subjects with complete loss of motor function following spinal cord injury. After lesions to descending spinal pathways that result in a complete loss of motor function, patients often experience spasticity, loss in bone density, and a number of other secondary complications. We believe that intensive locomotor training with the Lokomat robotic gait orthosis (Hocoma, Inc., Zurich Switzerland) will lead to reductions in these negative health complications since this therapy promotes dynamic loading of the bones, increases in circulation, and continuous ranging of joint motion. As a result, we postulate that subjects who train on the device will experience improvements in health status and consequently improvements in quality of life.

Project C1: Stroke Performance Recovery and Outcomes Study

Stroke Performance Recovery and Outcomes Study examined specific patient characteristics and rehabilitation interventions and their relationship to outcomes. All together, six inpatient rehabilitation facilities in the U.S. and one in New Zealand contributed detailed patient-level data on 1,291 patients-approximately 200 consecutively admitted stroke patients from each site. The study entailed the development of a detailed taxonomy of interventions, the creation of extensive in-depth data collection protocols, the creation of a study database, data analyses, publications, presentations, and project spin-offs to exploit the database. The study was made possible by a cohesive leadership team, the commitment by participating clinical sites, and a number of volunteer investigators who have joined the study as it became better known throughout the country and aboard.

Project C2: Role of Eye Movements in Activities of Daily Living

This was a feasibility study with the long-term goal of identifying and characterizing deficits in the integration of manual and gaze behavior, by individuals recovering from brain injury, in activities of daily living, in order to target rehabilitative and assistive interventions. The immediate goals of this pilot were to determine whether the body-worn, mobile eye tracking technology can be used without itself unduly affecting people's behavior, and, whether data acquired by using this technology shows promise of uncovering and providing a way to quantify, interesting difference between the gaze behavior of brain injured individuals and non-disable controls.

The two main objectives for this study included development and feasibility of a wearable eye-tracking system.

Development of a wearable system that tracks gaze-angle, records the scene, relates gaze to target and yields accurate, objective data included a review of existing technology and determining whether to replicate current systems used by other investigators.

The device selected for the project was one of the mobile systems manufactured by Applied Science Laboratories (ASL), the Mobile 501. This device is designed for use in

situations in which the wearer must have complete freedom of movement. The control unit, optional VCR, and video transmitter are mounted in a backpack, and a heavy power belt is worn around the waist.

The data consists of videotape showing the position of a cursor, representing point of gaze, superimposed on the videotape of the scene in front of the wearer. This image is also transmitted to the scene monitor for review by the system operator. The Mobile 501 system is shown in Figure 2 below.

FIGURE 2 THE ASL MOBILE 501 SYSTEM.

Trials of the system to develop skill and assess comfort resulted in the identification of aspects that were not comfortable. Modification was made to the battery belt and back pack. The modifications allow the pack to have an even distribution of weight, while the straps hold it close to the body to reduce moment arm and improve comfort. See figure 3.

FIGURE 3 THE SYSTEM AS MODIFIED FOR USE IN THIS PROJECT.

A technique was developed to allow rapid, reliable calibration in the Independence Square kitchen. Also, methods were developed to keep the considerable amount of equipment specific to the project (including additional lamps, in place of bright overhead lighting that produced overexposed video) organized and able to be deployed and repacked rapidly.

Feasibility test of the system with healthy controls and with patients who have marked executive function deficits have been initiated

Data Reduction:
Each frame of video (collected at 30 frames/sec) in which the face of the participant is visible is being processed to obscure the face and render the individual non-identifiable.

A method has been developed for enumerating and noting order and duration of fixations on objects during performance of each task, and for similar categorization of manual behaviors. This method is being used to reduce the data on the videotapes.

Project D1: Determining the Psychometric Properties of the NRH Pragmatic Communication Skills Rating Scale

Speech-language pathologists (SLP) completed the NRH Pragmatic Communication skills Clinician Rating Scale as part of their evaluation of right-hemisphere stroke survivors. Family members or significant others were asked to fill out the version of the same scale that has been designed for their use. Both of these rating scales have been used clinically without benefit of reliability or validity testing. Reviews of work done with this scale to date had been extremely encouraging, with the caveat that the psychometric properties of the Scale need to be examined. The objective of this project was to determine the reliability and validity of the clinician scale in order to contribute to the profession, current clinical practice and the ability to conduct applied research regarding pragmatic communication changes after stroke in a multi-cultural population.

Project D2: Metabolic Studies in Individuals with Chronic Spinal Cord Injury: The Effects of an Oral Anabolic Steroid and Conjugated Linoleic Acid

This study investigated the effects of Oxandrolone in individuals with chronic spinal cord injury (SCI). Oxandrolone is an oral anabolic steroid that has been shown to increase lean body mass and improve pulmonary function in this population. A total of ten subjects were studied to determine if Oxandrolone improved lean body mass and pulmonary function in individuals with T4-C4-ASIA A or B SCI of at least one year duration. We obtained liver function tests (LFTs), lipid panel, pulmonary function test (PFTs), and dual x-ray absorbtiometry (DEXA) for body composition analysis on subjects as a baseline, during and immediately after the intervention and then three months later to determine if any changes are maintained. For the intervention, participants took eight weeks of Oxandrolone 10 mg BID. Subjects were closely monitored for any adverse events related to the study medication during clinic visits and by regular weekly telephone contact and pre-and post-treatment differences were calculated and baseline values were compared to control and other tetraplegic populations.

Project D3: Development and Clinical Validation of a Children's Version of the Automated Neuropsychological Assessment Metrics (ANAM)

Every day children experience illnesses, injuries, or take medicines that may change their ability to think quickly and remember things. This study adapted and validated a group of computerized tests, called the Automated Neuropsychologic Assessment Metrics (ANAM), in order to inform doctors and other health care providers when a child had a change in his or her cognitive functioning. The ANAM battery was originally developed by the US Army to measure changes in thinking abilities in adults. While ANAM has been used with young adults and adolescents in high school, it has not been used with children younger than 13 and a comparable measure in this age group does not exist.

The study included three stages. The first stage included development and pilot testing of a pediatric version of ANAM (ped-ANAM) with children between the ages of 10-12, to demonstrate that children at this age can understand and complete the test. During the second stage, a group of middle school children (between the ages of 10-12) took ped-ANAM. This phase of the study established expected levels of performance in normally developing children and test for differences in performance between boys and girls and across the three age ranges. In the last stage of this project, sensitivity of ped-ANAM to detect cognitive change in two pediatric clinical groups examined a series of single subject studies.

The specific aims of the study were:

- Develop and test the feasibility of a pediatric version of the Automated Neuropsychological Assessment Metrics (ped-ANAM) to be used with children ages 10 – 12.
- Evaluate the psychometrics of ped-ANAM, including measures of test-retest reliability, practice effects, and concurrent validity with neuropsychological testing.
- Determine the normative performance and typical variability of ped-ANAM across ages 10 - 12.
- Examine developmental trends and sex differences observed on ped-ANAM.
- Demonstrate the sensitivity of ped-ANAM to detect cognitive change related to medication in children with Attention Deficit Hyperactivity Disorder being treated with psychoactive medications for attentional impairment.
- Demonstrate the use of ped-ANAM to monitor cognitive recovery in children who have sustained a mild traumatic brain injury.

Project D4: "Does Constraint-Induced Movement Therapy Improve Upper Extremity Motor Function in Individuals Following Stroke?"

Stroke has recently been estimated to affect 730,000 persons per year in the United States, with cost estimates ranging from 13-30 billion dollars.(1) Although most stroke survivors partially recover, recovery often leaves the individual with significant sensorimotor and cognitive deficits. Constraint Induced Movement Therapy(CIMT) (2;3) is a strategy of rehabilitation as applied to hemiparesis consists of directing the patient's direct attention and effort to the use of the affected upper extremity (UE). Redirection occurs by engaging in exercises designed to increase attention, strength and functional use on the affected side while immobilizing the unaffected upper extremity (UE) for several hours a day to discourage its use. Compensatory strategies involving the unaffected side are discouraged. A series of small studies has examined CIMT in the chronic setting; most studies have been guardedly positive, but none has been designed to yield Level I data for evidenced-based practice(4-7). EXCITE(8), a trial of CIMT in the 90-180 day window (PI Wolf) does not examine persons beyond the period of spontaneous recovery.

The long term goal was to gather the data necessary to design a subsequent multicenter RCT of CIMT for various chronic stroke subpopulations. The protocol that was used in this study was based heavily on one developed by the PI at Washington University in St. Louis for the VECTORS (Very Early Constraint Treatment for Recovery from Stroke) study, an NINDS funded study of CIMT during the inpatient rehabilitation phase of stroke care. That study completed accrual without any safety issues. The primary result of VECTORS was reported in the 2007 International Stroke Conference. The group that received CIMT did equally well as the group that received a dose-matched traditional treatment. Thus, CIMT was shown to be safe and effective, but not superior to traditional treatment in the inpatient setting. VECTORS only enrolled subjects with pure motor hemiparesis, and specifically excluded persons with substantial sensory loss and neglect. However, in the chronic stroke population, this was the group that responded best to CIMT (VanderLee, 1999).

Project E1: Annual Project Conference

The Stroke Outcomes Conference showcased findings from the Stroke Performance Recovery and Outcomes Study more popularly known as the Post-Stroke Rehabilitation Outcomes Project (PSROP) and encouraged participants to explore how study findings could contribute to additional research, practice implications, and policy implications. Over 20 publications from the PSROP have appeared in the peer-reviewed literature, including 12 articles in the *Archives of Physical Medicine and Rehabilitation Supplement*, December 2005. This Supplement was provided to each conference participant. PSROP used a practice-based evidence (PBE) approach. The purpose of this conference was to discuss study methods, key findings, best practices, and new opportunities for multi-center studies both in the US and abroad.

Project E1: Workshop on current and future aspects of Upper – Limb Amputation Rehabilitation and Prosthetic Training.

The National Rehabilitation Hospital (NRH) Neuroscience Research Center organized a workshop addressing the current issues associated with upper limb amputation rehabilitation, along with the numerous challenges encountered with upper – limb prosthetic training. The meeting served as a forum to discuss future research endeavors that could advance the field of upper extremity amputee care and prosthetic use. The event was open to the public and was attended by consumers, clinical specialists (i.e. Occupational Therapist & Physical Therapist), Physicians, Researchers, and Prosthetists.

Project E2: Expert Panel on Neuroprotectant Treatment of Mild Brain Injury

The panel reviewed candidate neuroprotectants in order to produce one of two actions: 1) a state-of-the-art literature review of neuroprotectants, with the conclusion that none are promising for current clinical trials, or, 2) the identification of one or more promising neuroprotectants, with the conclusion that a clinical trial should be undertaken. In the event of the latter conclusion, the literature review will serve as the introduction for a clinical trial research proposal.

Project E3: Expert Panel to Explore Feasibility of Neuro-imaging Studies

There has been very little work to date addressing the anatomic substrates of self-awareness in adults with brain injury. Functional neuro-imaging has become widely used in research applications, though clinical uses for this technology remains very limited at this point. The purpose of this project was to consult with experienced investigators in the area of functional neuro-imaging, with the goal of determining the

feasibility of applying such techniques to self-awareness studies following brain injury. Consultations were be done on the basis of individual contacts rather than a convened panel. A written summary of conclusions that emerge from this project were prepared, and used to guide possible future functional neuro-imaging studies.

SUMMARY OF CONFERENCE PRESENTATIONS

Sections of this conference's executive summary were used to complete this report.

Introduction to Stroke Outcomes Conference (G DeJong)

Dr. Edward Healton, Medical Director at NRH, joined Dr. Gerben DeJong in welcoming conference participants to this dissemination conference and acknowledged the many contributions of facilities that participated in the Post-Stroke Rehabilitation Outcomes Project.

Participating facilities:

- The National Rehabilitation Hospital
- The University of Pennsylvania Medical Center
- LDS Hospital Rehab Center
- Legacy Health System
- Loma Linda University Medical Center
- Stanford University Hospital
- Wellington/Kenepuru Hospitals

The U.S. Army & Materiel Command and the National Rehabilitation Hospital Development Office provided funding for this working conference. Staff support was provided by the NRH Development Office, the NRH Research team, and ISIS-ICOR.

The conference began with an introduction of research methods used in the PSROP, provided details about the sentinel findings, and most importantly, set the stage for continued research, practice, and policy, implications, and international collaborations.

Going Beyond the Holy Grail of the RCT (S Horn)

The PSROP uses a practice-based evidence (PBE) method that examines current practice variations to identify best practices. The PBE study methodology provides a naturalistic view of rehabilitation practice by examining what happens in the process of care and allows us to disassemble the components to determine how and to what degree each component contributes to outcomes. Most previous studies have looked at post-stroke rehabilitation in the aggregate without disassembling the components to determine which specific components contribute to the outcome. This method enables researchers, working with clinicians, to identify the processes of care that work best for specific types of patients.

A PBE study is non-experimental, inclusive, and pragmatic in that it follows the outcomes of treatments prescribed to patient populations undergoing routine care. It

can study simultaneously outcomes of a large variety of treatments and ask complex questions regarding treatment sequence effects and conditional effectiveness.

Unlike the randomized controlled trial, PBE bases its approach on local clinical knowledge to connect outcomes with detailed process steps. PBE data allow an investigation of the effectiveness of treatment combinations on outcomes while controlling for patient differences. It also permits a discovery of practices associated with better functional and clinical outcomes at lower cost.

PSROP Taxonomy, Methods and Baseline Results (J Gassaway)

The PBE approach used in the PSROP exemplified participatory action research. It assembled a clinical practice team (CPT), which included physicians, physical and occupational therapists, speech and language pathologists, nurses, social workers, psychologists, and recreational therapists (direct care providers) from each participating facility to develop the study design, define variables, and provide clinical expertise to the analysis process.

The global study questions were:

1. Which *patient characteristics* are associated with improved post-stroke outcomes?
2. Controlling for patient characteristics, which *treatment interventions* or combinations are associated with improved outcomes?
3. What is the *optimal intensity and duration* of various post-stroke treatment interventions?

The clinical practice team determined relevant outcomes: change in FIM score, discharge FIM score, change in severity of illness, discharge severity of illness, discharge disposition, mortality, repeat stroke, deep vein thrombosis, anemia, pulmonary embolism, falls, pneumonia, and mental disorders. Patient variables included age, gender, race, payer source, type and side of stroke, stoke location, admission FIM (total, motor, cognitive), case-mix group (CMG), admission severity of illness, acute care hospital length of stay (LOS), and date/time of stroke symptom onset. The main process variables were rehabilitation LOS, medications, nutrition, pain management, time to first rehabilitation, oxygen use, and specific therapy activities and interventions including their intensity, frequency, and duration of therapy interventions.

Approximately 200 patients from each of the six US sites were admitted consecutively during the data collection period (March 2001-March 2003). Two data collection methods were used. The first was point-of-care documentation. Clinicians were trained to complete point-of-care documentation forms (developed by the clinicians themselves) for each therapy session, nursing shift, and interaction/assessment for each study patient. The second data collection method was post discharge chart review. Data abstractors reviewed chart documentation for Comprehensive Severity Index (CSI) and other patient, process, and outcome variables.

Analytical approaches included bivariate analysis, Pearson and Spearman correlation, and multiple regression analysis. Clinical experts from the CPT participated iteratively in the analysis process by suggesting ways to aggregate and explore the data. They also provided clinical advice about how to interpret study findings.

Major Findings

- Significant site variation was found in many patient variables: race, payer, stroke risk factors, type and side of stoke, FIM scores, severity of illness, and CMG.
- Significant site variation also was seen in process variables: rehabilitation LOS, PT intensity, OT intensity, SLP intensity, tube feeding use, and medication use.
- When time spent in specific therapy activities per day (rather than total time spent per day by a therapist type) was allowed to enter regression equations, the explanatory power to predict specific outcomes increased.

Implications / Next Steps

- Additional analyses of PSROP database are warranted.
- Findings should be put into practice and studied in an implementation project.

The Leap-Frog Hypothesis: Is Early and More Aggressive Therapy Better? (B Conroy)

A major consistent finding throughout PSROP analysis was the association of early and more functionally complex treatments with improved outcomes. Examples include earlier engagement in neurodevelopmental activities, earlier use of psychotropic medications, earlier engagement in upright activities, and earlier use of gait activities. A more detailed description of findings within specific disciplines can be found in the workgroup summaries below.

Analysis outputs were shared to demonstrate the complexity of regression analyses that control for many patient and process variables. The Clinical Practice Team was challenged to suggest analyses that would disprove specific findings, e.g., how more gait training in the first three hours of physical therapy was associated with more improvement in functional FIM or use of opioid medication was associated with better outcomes. However, the findings of early use of more functionally complex treatments were consistent throughout analyses that included challenges from the Clinical Team.

Major Findings

- More time in high-level therapy activities in the first 3 or 4 hours of rehabilitation therapy, e.g., more gait for low-level ambulators (FIM walk score = 1 on admission) was associated with greater likelihood of higher discharge FIM walk score and of being discharged to home
- Use of opioid analgesics was associated with better outcomes
- Use of antipsychotic and/or antidepressant medications associated with better functional outcomes.

Practice Implications

- Get patients into upright, gait training situations as early as possible.
- Make more frequent use of atypical antipsychotic medicines for patients who may have agitation or nighttime confusion
- Physicians can feel more comfortable using narcotic analgesics
- Physicians change style of documentation to portray education and counseling components rather than just physical assessments, e.g., BP and diabetes are controlled

Next Steps

- Determine predictive validity of findings: implement PSROP findings and evaluate whether outcomes observed are those predicted

WORKGROUP PRESENTATIONS AND DISCUSSION

Conference participants self-selected one of two workgroups to discuss specific PSROP findings, especially whether earlier and more aggressive treatment is better, and recommendations for practice, policy, and research. Each workgroup presentation is summarized below.

Physical and Occupational Therapy (N Latham & L Richards)

Findings

- More functionally complex therapy earlier in the rehabilitation process is associated with better functional recovery, even for patients with low admission FIM scores. Gait activities initiated within the first three hours for patients admitted at FIM walk level 1 were associated with greater likelihood of attaining FIM walk level 4 or higher on discharge and to be discharged to home.
- Over 80% of PSROP patients were discharged to the community, however, the majority of them received no community mobility training.
- OTs spend much time in Basic Activities of Daily Living (BADLs) and upper extremity (UE) control and very little time in higher-level intervention activities.
- There is no significant difference in mean time spent on UE dressing and UE control.

Additional analyses suggested for PSROP Data

- Describe the patient populations who receive more functionally complex therapy in greater detail. To do this, we must first define 'functionally complex therapy.' Current regression models use amounts of time spent in specific activities in blocks of therapy after admission; we need to define thresholds for amount of time spent in complex therapy – any time, minimum two hours, etc. Patient factors to allow to enter in these analyses include cognitive impairment, aphasia, height/weight, family support, etc.

- Analyze interventions within activities to help better understand therapy-specific intervention components within each activity. Conduct additional analyses of incremental interventions.
- Determine if patients who received less functionally complex treatments were admitted on Fridays.
- Analyze the data to determine if a sampling of POC forms, e.g., take every fourth encounter, gives the same information [multiplied by 4] as data contained in all the forms to determine if an implementation study would require the same amount of documentation.
- Analyze psychological factors in PSROP more carefully.
- Determine if the definition of OT community mobility training could explain why this OT activity was used so seldom?

Notes:

a. Current regression analyses allowed many patient variables to enter the models, but they were not significant in predicting specified outcomes. These patient variables include: lesion location, stroke location and type (hemorrhagic vs. ischemic), aphasia, cognitive impairment, height/weight, race, age, etc.

b. Type of therapist (aide, PTA, etc.) was examined but much data were missing. Also, analyses were performed at the patient level in blocks of therapy time; several different types of therapists can treat individual patients. To examine therapy provider type we would have to consider session-level analyses rather than blocks of 3 or 4 hours of therapy.

New and additional studies

- Include persons with stroke in long-term acute care and SNF facilities.
- Develop a portfolio for measures of impairments that are more descriptive than the Functional Independence Measure (FIM). The therapy workgroup noted that the FIM does not reflect adequately a patient's true functional status; recommended looking beyond the FIM in evaluating functional status.
- How do PT and OT influence longer term functional and participation outcomes?
- Do facility resources (supplies, equipment, staffing) affect choice of therapy?
- How can an OT restore impairment function vs. teaching compensatory techniques with constraints in the length of stay?

Implications for practice and policy including accreditation

- Medicare and policymakers use FIM as standard measure of function. A better tool could, and should, be developed.

Speech and Language Pathology (B Hatfield)

Findings

- There is a greater likelihood of a better outcome when mid-level and cognitive linguistically complex activities (including high-level problem solving) are done in the first three-hours of treatment.

Additional analysis of PSROP Data

- Examine aphasia, dysphagia, and dysarthria for associations with outcomes.

Implications for practice and policy including accreditation

- Patients with low linguistic ability on admission appear to benefit from high-level tasks early in treatment; may need more cueing/assistance to complete tasks.

Next steps

- Correlate findings with standardized test scores for admission and discharge

Timing of Initiation of Rehabilitation after Stroke (D Ryser & R Smout)

Findings

- Earlier transfer to rehabilitation is associated with better discharge function (for moderate (CMG 104-107) and severe stroke (CMG 108-114)) and a shorter LOS (for moderate stroke).
- Earlier transfer is not the largest determinant of functional outcome but it is the one, beside rehabilitation LOS that can be modified. The severe stroke group had the strongest association between earlier transfer and better outcomes, suggesting that early rehabilitation transfer does not harm the injured brain.

Additional analysis of PSROP Data

- Analyze ischemic stoke patients separately from hemorrhagic stroke patients. Perhaps ischemic stroke patients do not need diagnostics typically obtained in acute care.
- Identify patients with specific comorbidities that may benefit from earlier admission to rehabilitation.
- Examine Elliot Roth's study about what contributes to time from onset of stroke symptoms to rehabilitation and replicate with PSROP data if possible.

Implications for practice and policy including accreditation

- Encourage Medicare, VA, DOD health plans and other health plans to facilitate earlier admission.
- Allow rehabilitation providers to admit patients directly from the ER without reimbursement penalization.
- Bring ambulatory rehabilitation teams into stroke units.

Nursing – Going Beyond the Commode (L Sims & R Hill)

Findings

- More RN analyses of functional ability and more RN discharge planning time are associated with shorter lengths of stay.
- More time spent on RN activity of community reentry is associated with longer lengths of stay.

Additional analysis of PSROP Data

- Examine the amount of time spent in specific nursing activities and how this relates to outcomes. Establish a nursing "block" of time similar to the approach used with therapists
- Examine the number of times nurses bring an issue to a doctor's attention. Many nurses did not include this in the team process but we could look on the MD forms to see the amount of time spent in nursing discussion.

New and additional Studies

- Determine if nursing interventions, especially education, are related to better six-month outcomes.
- Obtain a better understanding of which nursing practices affect outcomes. Much of the nurse's time is consumed by tasks that do not impact the outcomes we studied.
- Capture the "out of bed" time spent sitting up.
- Improve methods of collecting nursing data.

Implications for practice and policy including accreditation

- Nursing could become involved in initial ongoing assessment processes such as dysphagia screening traditionally done by therapists. Nurses would continue to monitor status throughout the stay.
- Make efforts to obtain funding to work with patients after they are discharged.

Exploration of Medication Use and Outcomes (B Conroy)

Findings

- Opioid narcotic use was associated with better outcomes.
- Antipsychotic and/or antidepressant medication use was associated with better functional outcomes.
- SSRI use was associated with better functional outcomes (the newer SSRIs are better than the older SSRIs)

Additional Analysis of PSROP Data

- Examine the affect of fatigue the day following hypnotics.
- Examine how age and use of narcotics are associated with the occurrence of falls.
- Examine how opioid timing and dosing are associated with the pain scale. Are there associations with use patterns? What kind of pain is treated with opioids? Does site variation continue when combined with use patterns?
- Add timing to the Zyprexia analyses.
- Examine behavior changes relative to the start and stop of neurostimulant use. Are poorer outcomes associated with patients who need neurostimulants from the onset (belief that they won't get better)?

Enteral Nutrition as a Rehabilitation Outcome (D Gines & R James)

Findings

- Patients who were tube fed had better outcomes (including patients with pneumonia). Tube feeding patients may allow time for adequate nutrition. Patients may rush their meals because therapy or other interventions take precedence.
- There was significant site variation in enteral feeding support and in monitoring nutritional status.

Additional analysis of PSROP Data

- Associate behaviors, tube feeding practice (yes/no), and medication use (ativan vs. anxiolytics) with specified outcomes.
- Distinguish between types of feeding tubes used.
- Determine if each site had a stroke visitor program.
- Examine BUN/creatinine to determine hydration status.
- Examine the effect of tube feeding in combination with SLP/Nursing therapeutic feeding.

New and additional Studies

- Explore differences in nutritional intake for comparable patients who do and do not receive tube feeding by collecting complete intake data.
- Explore causes of aspiration to assess the association of tube feeding and pneumonia. Include oral care details because the bacterial source for most aspiration pneumonia is saliva.

Implications for practice and policy including accreditation

- Encourage each rehabilitation unit to have their own protocol for nutrition management. Enforce routine monitoring of nutrition status (weight, intake, tolerance, labs per unit protocol).
- Increase staff training/recognition of the importance of nutrition as a rehabilitation therapy.
- Ensure that prescribed diets fit the ability of the patient to eat thereby ensuring the reaching of goals (including kcal counts) or early supplementation of PO (TF or other) if goals not met.

SUMMARY OF CONFERENCE PRESENTATIONS: INTERNATIONAL STUDIES

Stroke Rehabilitation Practice in New Zealand and the U.S. (H McNaughton)

The European CERISE Study (K Putman)

A detailed analysis was performed on the comparison of recovery between the PSROP six US-centers and the two centers in New-Zealand (NZ). NZ patients were older, less independent, and more likely to live alone prior to stroke compared to US patients. On admission, US patients were more severely disabled compared to NZ patients.

Structure and processes of care were compared also. The average length of stay of US patients was significantly shorter compared to NZ patients but they received more therapy (in total hours). Significant differences were not seen on the total FIM score but discharge disposition was more likely to be home for US patients. The question on long-term efficiency remains unanswered as long-term comparison is yet to be done.

The Collaborative Evaluation of Rehabilitation In Stroke across Europe study - CERISE (2002-2006) focused on the comparison of functional and motor outcome between five stroke rehabilitation units (SRU) in four countries. Case-mix differences on admission were found between the SRUs and were explained partly by different appraisals of clinical characteristics of the patients. Also non-clinical patient characteristics and factors related to referring networks determined who was admitted to the SRU. After controlling for case-mix, significant differences in motor and functional recovery were found between the SRUs. Large differences were found for average time stroke patients spent in therapy. The proportion of time occupational therapists and physiotherapists spent on direct patient care was very different between the SRUs. One of the underlying reasons was found in the amount of time spent on administration, team conferences, and ward rounds. Content of individual OT and PT sessions was also studied but only few differences between units were found. It is likely that the differences in recovery between SRUs are linked with differences in process of care rather than with differences in clinical interventions.

Need for international research

Stroke rehabilitation services are embedded in health care systems creating contextual constraints with various (dis)incentives that vary across countries. SRUs organize their services to provide the best possible care within these constraints. Therefore, much variation in the organization of inpatient care can be expected between countries. This makes an international, straightforward comparison on outcome difficult. On the other hand, these variations create an opportunity to study organizational issues in relation to functional and motor outcome.

International comparisons needs to be taken further than outcome comparison at discharge. Long-term effects of treatment in specialized stroke units are studied frequently by measuring outcome 2 to 10 years after stroke onset. Differences in outcome between groups of patients are attributed to differences in treatments during the post-acute period. However, supporting services during the period between discharge and the time of outcome measures are not documented. Consequently, interpretation can be biased because of the unknown input of services in the post-discharge period.

In the PSROP study, the PBE approach enabled examination of patient characteristics, processes of care, and outcome measurements simultaneously. This comprehensive measurement framework provided a basis for meaningful analyses of associations between process and outcome, controlling for patient differences. The PBE methodology can offer a solution for a context-sensitive approach in international

comparison. One step has already been made in the form of concrete collaboration between the PSROP-study and CERISE-study. Both databases are combined enabling analysis of the effect of structure and process of care on functional outcome in a larger sample and to acquire new insights on the interactions between these elements in the care process.

Plan:

Continued analysis of PSROP database

- Describe the patient population who receive more functionally complex therapy in greater detail. To do this, we must first define 'functionally complex therapy.' Current regression models use amounts of time in specified activities; we need to define thresholds for amount of time spent in complex therapy – any time, minimum two hours, etc.
- Analyze interventions within activities to help us better understand therapy-specific intervention components within each activity.
- Analyze PSROP data to determine if a sampling of point-of-care documentation forms, e.g., take every fourth encounter, gives the same information [multiplied by 4] as data contained in all the forms to determine if an implementation study would require the same amount of documentation.
- Examine psychosocial factors more carefully. Include potentially motivating factors, such as family complexity and social support. Look at patients with perception deficits separately form those without perception deficits.
- The therapist workgroup suggested using the term "more complex treatment" or "more functionally complex treatment" instead of "more aggressive treatment" would better describe rehabilitation services.

Additional research implications /suggestions

- Allocate funding for an implementation study of PSROP findings.
- Conduct multi-setting studies that include inpatient rehabilitation facility (IRF), long-term acute care (LTAC), and skilled nursing facility (SNF) patients.
- Develop a portfolio for measures of impairments that are more descriptive than the Functional Independence Measure (FIM). The therapy workgroup felt that the FIM does not reflect a patient's true functional status; a different or new functional assessment tool would facilitate measures of level of function and progress.
- Use randomized control trials to test and determine predictive validity of select findings.
- Include a consistent measure of stroke severity, e.g., NIH Stroke Scale. CMGs are a measure of disability severity, not stroke severity. The NIH Stroke Scale used frequently, e.g., daily, could help measure and control for natural recovery.

Practice implications

- Initiate high-level therapy interventions early in the rehabilitation process, even for low-level functioning patients.

- Make more frequent use of atypical antipsychotic medicines for patients who may have agitation or nighttime confusion.
- Physicians can feel more comfortable using narcotic analgesics.

Policy Implications

- Encourage CMS, VA, DOD health plans (e.g. Tri-Care) and other health plans to fund earlier rehabilitation.

KEY RESEARCH ACCOMPLISHMENTS

Project A1: A Computerized Neuropsychological Battery for Parkinson's Disease: Application for Population Surveillance, Early Detection, and Monitoring Disease Progression

- Comparing subjects pre-medication and post-medication the results for Finger Tapping speed show significance at the $p<.02$ level for tapping speed, and for intertap interval at the $p<.04$ level.
- Regarding the Target Acquisition task, the primary significant variable proved to be initiation time, which was significant at the $p<.02$ level. Data were analyzed using means and medians.
- Parkinson's patients were strikingly variable in performance, with numerous outlier variables distorting the means.
- We found that data analysis using medians produced far more stable and orderly results and recommend that this be the method of choice for future research.

Project B1: The Impact of Self-Awareness on Functional Outcomes Following Moderate and Severe Traumatic Brain Injury

- Completed data collection and established database for subsequent analyses.
- 70 subjects enrolled in spite of the fact that the study research assistant left NRH for other employment.
- All data have been entered into the SPSS database for pending analysis and manuscript preparation
- Presentation of a peer-reviewed poster at a national neuropsychology conference.
- The self-awareness instrument (FSAS) is both reliable and practical for use in clinical practice by clinicians across a range of disciplines.
- Self-awareness deficits early following brain injury can be effectively assessed using the FSAS, which allows for further understanding of the phenomenon as well as systematic measurement of the efficacy of interventions to address awareness.
- Preliminary data analyses suggest that early assessment of awareness using the FSAS is predictive of functional outcome and self-awareness six months later.

Project B2: Gait Restoration in Stroke and Incomplete SCI Patients Using the Lokomat Robotic Treadmill System

- For the stroke component, we enrolled and trained 39 subjects at NRH while the Rehabilitation Institute of Chicago enrolled 23 subjects.
- The data from this study has been analyzed and accepted for publication in Neurorehabilitation and Neural Repair.

- We are in the process of writing a follow up paper that will report a co-variate analysis of the data. This will include looking at the influence of age, initial level of impairment, and time post-stroke to study entry on outcomes both within and across subject groups.
- The goal is to submit this manuscript by the end of 2008.
- For the SCI leg of this study, we trained a total of 3 individuals with SCI. We have completed the analysis of the data and are now preparing a manuscript. We have a first draft completed and anticipate submitting this for publication by September 1, 2008.

Project C1: Stroke Performance Recovery and Outcomes Study

- Our project team hosted the Stroke Outcomes Conference at the National Rehabilitation Hospital on September 8-9, 2007
- Our project team hosted, Koen Putman, PT, PhD, a Fulbright Scholar from the Free University of Brussels. The Project team worked with Dr. Putman in merging his data from a 5-center (from 4 countries) stroke rehabilitation outcomes study (N=535) with data from the Stroke Performance Recovery and Outcomes Study (N=1,291). We completed the data merge this past year and will begin to examine cross-country and cross-center practice and outcomes.

Project C2: Role of Eye Movements in Activities of Daily Living

- Several control participants were enrolled first, so that any difficulties with the procedure would come to light before experimental group participants took part.
- 10 controls and one individual recovering from brain injury completed the study.
- The data that had been analyzed thus far was intriguing, in that there is some indication of a relationship between Wisconsin performance considered primarily as an index of flexibility, and evidence from gaze behavior of planning, in what is, in all but one case, a non-clinical population!
- We hope to determine whether this apparent relationship between test scores of EF and use of gaze in planning will hold up in this non-clinical population. However, it is only by testing groups known to be at risk for EF deficits that the value of this technology for investigation and rehabilitation of EF impairments can be explored.

Project D1: Determining the Psychometric Properties of the NRH Pragmatic Communication Skills Rating Scale

- Results of data for 27/50 subjects that were collected was submitted to the Clinical Aphasiology Conference

Project D2: Metabolic Studies in Individuals with Chronic Spinal Cord Injury: The Effects of an Oral Anabolic Steroid and Conjugated Linoleic Acid

- Mean lean body mass (LBM) increased by 4% in arms and 2% in total body while fat decreased by 0.7% in arms and 1.4% in total body during oxandrolone intervention.
- At 20 weeks, LBM increased another 7.5% in arms and 2% in total body.
- On average, weight increased 0.6 % and combined measures of PFTs improved 2.2% during treatment.
- High density lipoprotein (HDL) decreased 27%, low density lipoprotein (LDL) increased 32%, and LFTs increased 9.7-65 .6% while on therapy but trended to baseline at 20 weeks.

Project D3: Development and Clinical Validation of a Children's Version of the Automated Neuropsychological Assessment Metrics (ANAM)

- Creation and initial validation of computerized cognitive testing software platform to be used in pediatric populations.
- Collection of initial normative data for this computerized battery on 47 children between the ages of 10-12.
- Determination of feasibility and usability of administering this testing battery to children in this age range.
- Determination of differences in performance based on gender and age.
- Demonstration of construct validity through comparison with concurrently administered traditional neuropsychological testing.
- Demonstration of utility and feasibility of using this computerized software in children with ADHD and traumatic brain injury.

Project D4: "Does Constraint-Induced Movement Therapy Improve Upper Extremity Motor Function in Individuals Following Stroke?"

- Gathered the data necessary to design a subsequent multicenter RCT of CIMT for various chronic stroke subpopulations.
- CIMT was shown to be safe and effective in ameliorating motor impairments but not visuospatial impairments in persons with chronic neglect.

Project E1: Annual Project Conferences

- Significant site variation was found in many patient variables: race, payer, stroke risk factors, type and side of stoke, FIM scores, severity of illness, and CMG.
- Significant site variation also was seen in process variables: rehabilitation LOS, PT intensity, OT intensity, SLP intensity, tube feeding use, and medication use.

- When time spent in specific therapy activities per day (rather than total time spent per day by a therapist type) was allowed to enter regression equations, the explanatory power to predict specific outcomes increased.
- More time in high-level therapy activities in the first 3 or 4 hours of rehabilitation therapy, e.g., more gait for low-level ambulators (FIM walk score = 1 on admission) was associated with greater likelihood of higher discharge FIM walk score and of being discharged to home
- Use of opioid analgesics was associated with better outcomes
- Use of antipsychotic and/or antidepressant medications associated with better functional outcomes.
- More functionally complex therapy earlier in the rehabilitation process is associated with better functional recovery, even for patients with low admission FIM scores. Gait activities initiated within the first three hours for patients admitted at FIM walk level 1 were associated with greater likelihood of attaining FIM walk level 4 or higher on discharge and to be discharged to home.
- Over 80% of PSROP patients were discharged to the community, however, the majority of them received no community mobility training.
- OTs spend much time in Basic Activities of Daily Living (BADLs) and upper extremity (UE) control and very little time in higher-level intervention activities.
- There is no significant difference in mean time spent on UE dressing and UE control.
- There is a greater likelihood of a better outcome when mid-level and cognitive linguistically complex activities (including high-level problem solving) are done in the first three-hours of treatment.
- Earlier transfer to rehabilitation is associated with better discharge function (for moderate (CMG 104-107) and severe stroke (CMG 108-114)) and a shorter LOS (for moderate stroke).
- Earlier transfer is not the largest determinant of functional outcome but it is the one, beside rehabilitation LOS that can be modified. The severe stroke group had the strongest association between earlier transfer and better outcomes, suggesting that early rehabilitation transfer does not harm the injured brain.
- More RN analyses of functional ability and more RN discharge planning time are associated with shorter lengths of stay.
- More time spent on RN activity of community reentry is associated with longer lengths of stay.
- Opioid narcotic use was associated with better outcomes.
- Antipsychotic and/or antidepressant medication use was associated with better functional outcomes.
- SSRI use was associated with better functional outcomes (the newer SSRIs are better than the older SSRIs)
- Patients who were tube fed had better outcomes (including patients with pneumonia). Tube feeding patients may allow time for adequate nutrition. Patients may rush their meals because therapy or other interventions take precedence.

- There was significant site variation in enteral feeding support and in monitoring nutritional status.
- The research team gained a deeper appreciation for the complexities associated with comprehensive rehabilitative care for the arm amputee.
- Study outcome measures were modified based on input from attendees with UL amputation.
- Workshop attendees were given community-based resources (i.e. support groups & recreation outlets) specific to the individual with upper limb loss.
- Develop research protocol for functional imaging studies with subjects from self-awareness project.
- Initial contact has been made with neuroimaging lab at Georgetown University.

REPORTABLE OUTCOMES

Project A1: A Computerized Neuropsychological Battery for Parkinson's Disease: Application for Population Surveillance, Early Detection, and Monitoring Disease Progression

An overall strategy and architecture for motor task development was developed in order to maximize compatibility across newly developed tests and facilitate future modifications. Consistent with ANAM philosophy, the motor test development strategy emphasizes flexibility for the examiner to modify test parameters and to select and aggregate specific motor tests into "batteries." Following development of the framework, the first motor task was prototyped. This task, the Alternating Two-point Target Acquisition subtest (ATPTA) has been completed.

Another element of test design strategy and architecture has focused on data structure and design, and automation of transfer of test data from data files to databases. Tests are designed using three programming logic groups, or "layers": user interface logic, business logic, and data logic. This was done so that future changes, whether they be in test parameters, operating systems, data management systems, etc., would not require complete redesign of the test, but only redesign of the specific logic section. We also have completed design and programming of preliminary templates for each logic section. These templates specify code requirements for new subtests, such that the additional motor tasks in our proposal already have a code "template" to assure that they will integrate seamlessly into our framework, as well as to provide a development map to expedite and increase the efficiency with which the additional tests will be developed. Moreover, since motor tasks can yield a nearly infinite number of test "scores," we have identified a set of preliminary output variables.

Access database was developed for purposes of data management and analysis.

Project B1: The Impact of Self-Awareness on Functional Outcomes Following Moderate and Severe Traumatic Brain Injury

Access database was developed for purposes of data management and analysis.

Publication and Presentations:

- Garmoe, W., Newman, A. & O'Connell, M. Self-Awareness early following traumatic brain injury: Comparison of brain injury and orthopedic impotents using the Functional Self-Assessment Scale (FSAS). Journal of Head Trauma Rehabilitation, 20(4), 348-358, 2005
- Garmoe, W., & Newman, A. C. The Functional Self-Assessment Scale (FSAS) in
- Measurement of Self-Awareness Early Following Severe Traumatic Brain Injury. Poster presented at International Neuropsychological Society (INS) annual convention, Portland, OR, February 2007.

Project B2: Gait Restoration in Stroke and Incomplete SCI Patients Using the Lokomat Robotic Treadmill System

We have published one manuscript on the stroke leg of the study and are now completing manuscripts on the SCI leg of the study and a follow up paper on the stroke results. These will be completed by Sept 1, 2008 and Dec 31, 2008 respectively.

Publication and Presentations:

A number of presentations and publications have resulted from pilot work done over the past funding cycle that was affiliated with this study:

Journal Papers

- J.Hidler, M. Zajacek, M. Carroll, E. Healton, and J. Dewald, "Reductions in differential control strategies at the hip and knee joints in acute stroke subjects," Biomedical Engineering Conference, Washington DC, 2002
- J. Hidler, D. Nichols, M. Pelliccio, K. Brady, D. Campbell, J. Kahn, and T.G. Hornby, "Multi-center randomized clinical trial evaluating the effectiveness of the Lokomat in sub-acute stroke." *In Review.*
- J. Hidler, W. Wisman, and N. Neckel, "Kinematic trajectories while walking within the Lokomat robotic gait-orthosis." *In Review.*
- R. Macko and J. Hidler, "Exercise after stroke and spinal cord injury: Common biological mechanisms and physiological targets of training." *Journal of Rehabilitation Research & Development*, Invited Guest Editorial, vol. 45(2), pp. vii-ix, 2008.
- J. Hidler, L. Hamm, A. Lichy and S. Groah, "Automating activity-based interventions: the role of robotics", *Journal of Rehabilitation Research and Development Special Issue*, vol. 45(2), pp. 337-344, 2008 (Co-edited issue with Richard Macko).
- J. Hidler, M Carroll, and E. Federovich, "Strength and coordination in the paretic leg of individuals following acute stroke" *IEEE Transactions on Neural Systems and Rehabilitation Engineering*, 15:4, 526-534, December 2007.
- N. Neckel, D. Nichols, M. Pelliccio, and J. Hidler, "Abnormal synergy patterns and weakness in individuals with chronic stroke." *Journal of NeuroEngineering and Rehabilitation*, 3:17, 2006.
- J. Hidler, D. Nichols, M. Pelliccio, and K. Brady, "Advances in the understanding and treatment of stroke impairment using robotic devices." *Top Stroke Rehabil*, vol. 12(2): 21-33, 2005.
- J. Hidler, "Inverse-Dynamics Based Assessment of Gait using a Robotic Orthosis", *IEEE Engineering in Medicine and Biology Society,* New York, NY, 2006.

- N. D. Neckel, W. Wisman, and J. Hidler, "Limb alignment and kinematics inside a Lokomat robotic orthosis", *IEEE Engineering in Medicine and Biology Society,* New York, NY, 2006.
- D. Nichols, N. Neckel, and J. Hidler, “Joint moments exhibited by chronic stroke subjects while walking with a prescribed physiological gait pattern”. *APTA 2007 Combined Sections Meeting*, Boston, MA, 2007.
- J. M. Hidler and A. Wall, “Changes in muscle activation patterns during robotic-assisted walking” In review.
- A. Ricamato and J. M. Hidler, "Quantification of dynamic properties of EMG patterns during gait.” In review.

Conference Proceedings

- J.Hidler, M. Zajacek, M. Carroll, E. Healton, and J. Dewald, “Reductions in differential control strategies at the hip and knee joints in acute stroke subjects,” Biomedical Engineering Conference, Washington DC, 2002
- J.M. Hidler, M. Oursler, G. Cooper and E. Healton, “Robotic-assisted gain training for restoring motor function in the lower limbs following spinal cord injury.” KMRREC Conference, Parsippany, New Jersey, 2002
- J M. Oursler, and J.M. Hidler, “Effects of walking speed and body-weight support walking ability in individuals with spinal cord injury,” APTA Annual Conference 2003
- J.M. Hidler, E. Healton, and M. Oursler, “Modulation of muscle activation patterns and reflex excitability with changes in walking speed and loading in individuals with spinal cord injury,” ASIA Conference, 2003
- J Hidler, “Robotic-Assessment of Walking in Individuals with Gait Disorders”, *IEEE Engineering in Medicine and Biology Society,* submitted.
- Wall and J. Hidler, “Alterations in EMG patterns during robotic-assisted walking”, *Northeast Bioengineering Annual Conference*, April 2004.

Abstracts

- A. Ricamato and J. Hidler, “A Tool to Quantify the Temporal and Spatial Properties of EMG Patterns during Gait”, *ISEK Annual Conference*, Accepted for June 2004.
- A. Lichy, J. Hidler, J. Cisper, and A. Wall. “Changes in muscle activation patterns during robotic assisted gait training.” *APTA Annual Conference*, Accepted for July 2004.

Invited Presentations

- "Contemporary Issues Surrounding Robotic-Assisted Locomotor Training", Neural Prosthesis Seminar Series, Cleveland FES Center, Cleveland, Ohio, May 2004.
- "Advances in the understanding and treatment of stroke impairment using robotic devices", CME Symposium - Stroke Rehabilitation: Outstanding Outcomes and Best Practices, National Rehabilitation Hospital, Washington, DC, May 2004.
- "Emerging technologies for understanding and treating motor-impairment in stroke and spinal cord injury", Neurosurgery Lecture Series, Washington Hospital Center, Washington DC, April 2004.
- Segmental control of walking: locomotor capacity of the spinal cord, Woodway USA Gait Training Workshop, Washington, DC, November 10, 2002
- Robotic-assisted treadmill training for restoring walking capability in spinal cord injury patients, National Institutes of Health, Rehabilitation Medicine Department Grand Rounds, September 6, 2002
- "Loss of differential muscle control leads to weakness and discoordination in individuals with acute hemiparetic stroke", IEEE Engineering in Medicine and Biology Society, Cancun, Mexico, September 2003.

Project C1: Stroke Performance Recovery and Outcomes Study

Publications:

- Gerben DeJong, Susan Horn, Julie Gassaway, Mary Slavin, & Marcel Dijkers (2003). "Toward a Taxonomy of Rehabilitation Interventions: Using an Inductive Approach to Examine the 'Black Box' of Rehabilitation." *Archives of Physical Medicine & Rehabilitation.* 55(April), 678-686.
- Deutsche, Anne, Carl V. Granger, Roger C. Fiedler, Gerben DeJong, Robert L. Kane, Kenneth J. Ottenbacher, Allen W. Heinemann, John P. Naughton, Maurizio Trevisan (2005) "Outcomes and Reimbursement of Inpatient Rehabilitation Facilities and Subacute Rehabilitation Programs for Medicare Beneficiiaries with Hip Fracture.: *Medical Care*. 43 (September) No. 9, 892-901.
- DeJong, Gebern (2005). "Medicare Reform and the American Devolution." Topics in Stroke Rehabilitation, 12 (2): 4-14.
- DeJong, Gerben and Susan Horn (2004). "Randomized Controlled Trials in Rehabilitation Research." *New Zealand Journal of Disability & Rehabilitation Research.* Submitted.
- Diane Jette, Nancy Latham, Randall Smout, Julie Gassaway, Mary Slavin, Susan Horn (2004)
- Zorowitz, Richard D., Smout, Randall J., Gassaway, Julie A., Horn, Susan D. (2005). "Prophylaxis for and Treatment of Deep Venous Thrombosis After Stroke: The Post-Stroke Rehabilitation Outcomes Project (PSROP)." *Topics in Stroke Rehabilitation* 12 (Fall), No. 4 1-10
- Zorowitz, Richard D., Smout, Randall J., Gassaway, Julie A., Horn, Susan D. (2005). "Antiplatlet and Anticoagulant Medication Usage During Stroke Rehabilitation Outcomes Project (PSROP)." *Topics in Stroke Rehabilitation* 12 (Fall), No. 4 11-19

- Zorowitz, Richard D., Smout, Randall J., Gassaway, Julie A., Horn, Susan D. (2005). “Antiplatlet and Anticoagulant Medication Usage During Stroke Rehabilitation Outcomes Project (PSROP).” *Topics in Stroke Rehabilitation* 12 (Fall), No. 4 20-27
- Zorowitz, Richard D., Smout, Randall J., Gassaway, Julie A., Horn, Susan D. (2005). “Neurostimulant Medication Usage During Stroke Rehabilitation: The Post-Stroke Rehabilitation Outcomes Project (PSROP).” *Topics in Stroke Rehabilitation* 12 (Fall), No. 4 28-36
- Zorowitz, Richard D., Smout, Randall J., Gassaway, Julie A., Horn, Susan D. (2005). “Usage of Pain Medications During Stroke Rehabilitation: The Post-Stroke Rehabilitation Outcomes Project (PSROP).” *Topics in Stroke Rehabilitation* 12 (Fall), No. 4 37-49
- “Physical Therapy Interventions for Patients with Stroke in an Acute Rehabilitation Setting,” *Journal of the American Therapy Association*. Submitted.
- Guest editors. The study’s PI and co-PIs were the guest editors of a special supplement to the *Archives of Physical Medicine & Rehabilitation*, December 2005 for 12 articles based on the findings of the Post-stroke Rehabilitation Outcomes Project (PSROP). NRH investigators also authored the following articles in the supplement.
- DeJong, Gerben, Susan D. Horn, Brendan Conroy, Diane Nichols, Edward Healton (2005). “Opening the Black Box of Post-stroke Rehabilitation: Stroke Rehabilitation Patients, Processes, and Outcomes.” *Archives of Physical Medicine & Rehabilitation.* 65(December),No. 12, Suppl 2, 1-7.
- Horn, Susan D., Gerben DeJong, David Ryser, Peter Veazie, Jeffrey Teraoka (2005). “Another Look at Observational Studies in Rehabilitation Research: Going Beyond the Holy Grail of the Randomized Controlled Trial.” *Archives of Physical Medicine & Rehabilitation* 86(December), No. 12, Suppl2, 8-15.
- Gassaway, J., Horn, S.D., DeJong, G., Smout, R., Clark, C., James, R. (2005). “Applying the CPI Approach to Stroke Rehabilitation: Methods and Baseline Results.” *Archives of Physical Medicine & Rehabilitation* (December), No. 12, Suppl 2, 16-33.
- Maulden, Sarah, Julie Gassaway, Susan D. Horn, Randy Smout, Gerben DeJong (2005). “Timing of Initiation of Rehabilitation After Stroke.” *Archives of Physical Medicine & Rehabilitation* 86 (December), No. 12, Suppl 2, 34-40.
- Latham, N., Jette D, Slavin M, Richards L, Smout R, Horn, S. Physical Theraphy During Stroke Rehabiltation for People with Different Walking Abilities. *Archives of Physical Medicine & Rehabilitation* 86(December), No. 12, Suppl 2, 41-50.
- Richards, Laurie, Nancy Latham, Diane Jette, Laura Roseberg, Randy Smout, Gerben DeJong (2005). “Characterizing Occupational Therapy Practice in Stroke Rehabilitation.” *Archives of Physical Medicine & Rehabilitation* 86 (December), No. 12, Suppl 2, 61-72.
- Conroy B, Zorowitz R, Horn S, Ryser D, Teraoka J, Smout R (2005).”An Exploration of Central Nervous System Medication Use and Outcomes in Stroke Rehabilitation.” *Archives of Physical Medicine Rehabilitation.* 86(December), No. 12, Suppl 2, 73-81.

- James R, Gines D, Horn SD, Gassaway J, Smout R (2005). Nutrituion as a Rehabilitation Intervention. *Archives of Physical Medicine Rehabilitation.* 86(December), No. 12, Suppl 2, 82-92.
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- Horn, Susan D, Gerben DeJong, Randy Smout, Julie Gassaway, Roberta James, Brendan Conroy (2005). "Stroke Rehabilitation Patients, Practice and Outcomes: Is Earlier and More Aggressive Better?" *Archives of Physical Medicine Rehabilitation.* 86(December), No. 12, Suppl 2, 101-114.
- McNaughton Harry, Gerben DeJong, Randy Smout, John Melvin, Murray A. GBrandstater (2005)."A Comparison of Stroke Rehabilitation Pracitce and Outcomes Between New Zealand and United States Facilities." *Archives of Physical Medicine Rehabilitation.* 86(December), No. 12, Suppl 2,115-120.

Presentations:

DeJong, G. "The Post-stroke Rehabilitation Outcomes Project." A presentation made to the International Stroke Rehabilitation Congress sponsored by CERISE (Collaborative Evaluation of Rehabilitation in Stroke across Europe) hosted by the Catholic University at Leuven. Leuven, Belgium. February 11, 2006.

September 8-9, 2008 Stroke Outcomes Conference
National Rehabilitation Hospital
Washington, DC

Project C2: Role of Eye Movements in Activities of Daily Living

The two main objectives for this study include development and feasibility of a wearable eye-tracking system.

Development of a wearable system that tracks gaze-angle, records the scene, relates gaze to target and yields accurate, objective data included a review of existing technology and determining whether to replicate current systems used by other investigators.

The device selected for the project is one of the mobile systems manufactured by Applied Science Laboratories (ASL), the Mobile 501. This device is designed for use in situations in which the wearer must have complete freedom of movement. The control unit, optional VCR, and video transmitter are mounted in a backpack, and a heavy power belt is worn around the waist.

The data consists of videotape showing the position of a cursor, representing point of gaze, superimposed on the videotape of the scene in front of the wearer. This image is also transmitted to the scene monitor for review by the system operator. The Mobile 501 system is shown in Figure 2 below.

Project D1: Determining the Psychometric Properties of the NRH Pragmatic Communication Skills Rating Scale

Publication and Presentations:
Prior research in this area and the current research design and rationale were presented at the Washington Hospital Center's Continuing Medical Education Symposium: Stroke Rehabilitation: Outstanding Outcomes and Best Practices, Washington, D.C., May, 2004.

Barone, C., Hatfield, B. and Georgeadis. A. (2005) Management of communication disorders using family member input, group treatment and telerehabilitaion. Topics in Stroke Rehabilitation, 12(2), 47-54

Project D2: Metabolic Studies in Individuals with Chronic Spinal Cord Injury: The Effects of an Oral Anabolic Steroid and Conjugated Linoleic Acid

Treatment with oxandrolone in healthy subjects with tetraplegia was associated with modest improvement in PFTs and in arm and total body LBM which continued to increase at 20 weeks. Baseline body mass composition was similar to other reports for individuals with tetraplegia and with more fat and less LBM than in controls. Abnormal changes in serum lipids and LFTs during treatment indicate that reported benefits of using oxandrolone in this population must be carefully weighed against potential adverse effects, especially with long-term use.

Publication and Presentations:

The Effects of a Trial with an Anabolic Agent in Healthy Persons with Tetraplegia: Case Series

Project D3: Development and Clinical Validation of a Children's Version of the Automated Neuropsychological Assessment Metrics (ANAM)

- Presentation of data to the ANAM Sports Concussion Working Group conference hosted at NRH in June 2006.

- Poster presentation and publication of abstract in conference proceedings at the National Academy of Neuropsychology to occur in October 2008 titled “Initial Validation of a Pediatric Version of ANAM.”
- Poster presentation at the American College of Rheumatology meeting 2007 titled “Diagnosis Of Childhood-Onset Lupus Neurocognitive Impairment In A Clinical Setting: Usefulness Of Computer Based Testing And Self-Report.”
- Poster presentation at the American College of Rheumatology meeting 2007 titled “The Pediatric Automated Neuropsychological Assessment Metrics (Ped-ANAM) in Childhood-onset Systemic Lupus Erythematosus (cSLE) - No Significant Practice Effect in First Three Trials.”
- Study has led to fruitful collaborations with other institutions and research groups seeking to utilize pediatric computerized cognitive testing (e.g., St. Mary’s Kids Hospital in New York and Cincinnati Children’s Hospital).
- Publication in peer reviewed journal, Arthritis Care and Research, based on study results and collaboration mentioned above: Brunner, H., Ruth, N.M., German, A., Nelson, S., Passo, M., Roebuck-Spencer, T.M., Ying, Y., Ris, D. (2007). Initial validation of the pediatric Automated Neuropsychological Assessment Metrics for childhood-onset systemic lupus erythematosus. Arthritis Care and Research, 57(7), 1174-1182.

Conclusion:

Results indicated that children in this age group were able to understand and complete the battery with low failure rates, defined by accuracy rates < 60%. Children showed the greatest failure rates on a test of mental manipulation of spatial information. Few differences in test performance were seen between boys and girls and across age. Strong correlations were seen between ped-ANAM subtests and neuropsychological tests. Results of performance in clinical populations have been supported in pediatric samples with Lupus based on separate studies that came about based on this study. Analysis of patients with ADHD and traumatic brain injury is forthcoming.

Project D4: “Does Constraint-Induced Movement Therapy Improve Upper Extremity Motor Function in Individuals Following Stroke?”

Preliminary results: Both subjects enrolled in the study tolerated the treatment well and demonstrated gains in arm motor function after the 2 week study period. Data were analyzed in conjunction with that collected at Washington University in St. Louis. Based on these analyses, we concluded that while CIMT was effective in ameliorating motor impairment, no effect on visuospatial neglect was detected.

Other Reportable Outcomes

- A stroke subject registry was developed. This registry captures data collected during the course of clinical care. These data are useful in identifying potential research subjects for subsequent research protocols, and for post hoc analyses. This database is an important new element of the NRC infrastructure.

- Preliminary data from this work was used to obtain funding for an NINDS-funded Phase III clinical trial on upper extremity restoration after stroke. This clinical trial (I-CARE, 1U01NS056256-01A2) commences enrollment Fall 2008.

Publication and Presentations:

- Dromerick, AW, Schabowsky CN, Holley RJ, Monroe B, Markotic A, Lum PS. "Effect of Training on Upper-Extremity Prosthetic Performance and Motor Learning: A Single-Case Study." *Archives of Physical Medicine & Rehabilitation.* 2008, 89(6): p.1199 -1204.
- Schabowsky CN, Dromerick AW, Holley RJ, Monroe B, Lum P. (2008) "Trans-radial upper extremity amputees are capable of adapting to a novel dynamic environment." *Experimental Brain Research*, 2008, 188 (4).

Project E1: Annual Project Conference

On May 14-15, 2004, Brendan E. Conroy, MD, Medical Director, Stroke Recovery Program, National Rehabilitation Hospital, convened the CME symposium, *"Stroke Rehabilitation: Outstanding Outcomes and Best Practices"* which was designed to provide clinicians with a comprehensive, current and practical approach to post stroke management. This two-day symposium was jointly sponsored by Washington Hospital Center (WHC) and National Rehabilitation Hospital (NRH) and was held at NRH. The activity featured national speakers (Pamela W. Duncan, PhD, and Gerber DeJong, PhD, both of University of Florida, Brooks Center for Rehabilitation Studies; and, Susan J. Ryerson, PT, MA, National Rehabilitation Hospital, in addition to participating MedStar Health faculty). The audience of approximately 125 attendees was a regional one of physicians, nurses, and allied health professionals, as well as physical therapists, occupational therapists, speech language pathologists, and case managers. Those in attendance represented the DC and Baltimore metropolitan areas and areas as far away as North Carolina, Missouri, Oklahoma, Massachusetts, and Tennessee.

A workshop entitled "Upper Extermity Amputee Workshop" occurred at the NRH on the 19th of May. Professionals representing multiple institutions were invited to discuss the clinical, psychosocial, and research aspects of upper-limb amputation. Institutions represented included the National Institutes of Health (Dr. Lin), Walter Reed Army Medical Center (WRAMC), District Amputee Care Center, Catholic University, and the UpperEx Peer Support Network.

The workshop was intended to provide a forum for consumers, clinicians, prosthetists, and researchers to discuss issues related to arm prosthetic use. Issues discussed included recognizing current advancements in prosthetic technologies; understanding the innovative training approaches utilized by therapists at the WRAMC; analyzing the research studies being conducted at NRH and the National Institutes of Health involving arm prosthetic use.

Two common themes emerged from the workshop:

1). The ongoing need for further rehabilitation research into the neuroscientific elements of prosthetic arm use.

2). The importance of more collaboration between interested parties to address the issues associated with prosthetic use and arm amputation.

Due to the success of this workshop, we intend to organize a similar event for the next calendar year.

- As a result of this conference, a VA RRD Merit review proposal entitled "Developmental studies for clinical trials of upper extremity amputee training" and underwent a promising review and has been resubmitted.

Project E2: Neuroprotectant Conference

The expert panel on neuroprotectant treatment of concussion was chaired by Dr. Kelly and consisted of the consultants listed above. Dr. Kelly met with each of the consultants at least twice both in person and electronically and produced a summary report which was delivered as a Grand Rounds at the National Rehabilitation Hospital, where it was recorded for Webcasting.

The overall conclusion of the panel was that a number of promising substances or under development in laboratories and war in clinical trials with pharmaceutical companies but that there were no currently available substances that met the requirements of efficacy and safety for current use. It was felt that the most prudent course of action was to continue monitoring of this topic at six-month intervals, given that promising substances likely would be available in the near future.

Project E3: Neuropsychology Conference

The Principal Investigator (Dr. Garmoe) attended fMRI workshops at the National Academy of Neuropsychology annual conference in 2003. In addition, he met with Dr. Frank Hillary, an experienced fMRI researcher (who at the time was at Kessler), to discuss feasibility of fMRI designs. Dr. Hillary affirmed the feasibility of fMRI protocols to investigate self-awareness, and possible collaboration was discussed. In early 2004 Dr. Garmoe initiated discussion with the director of the functional neuroimaging lab at Georgetown University (Dr. Zeffiro), who agreed to collaborate on designing studies. Following initial discussions, the project needed to be put on hold because of the priority of finalizing IRB approval for project B1 (which has been very lengthy through the Army IRB).

Other reportable outcome

The long term result of this effort was the initiation of a joint NRH-Georgetown University functional imaging collaboration. The first NRC subject underwent fMRI at Georgetown in Summer 2008. Initiation of an fMRI capacity, led by Drs. Dromerick and Lum at NRH and Dr. Van Meter at Georgetown, was a major developmental milestone for the NRC.

CONCLUSION

With the support of the USAMRMC, the Neuroscience Research Center at National Rehabilitation Hospital has achieved many successes, both those originally proposed as well as those subsequently developed in collaboration with USAMRMC as new information became available and as goals evolved.

Substantial progress has been made in developing active and productive research collaborations with educational, research, and clinical institutions in the Washington DC area. These institutions are both Federal and non-Federal. Training of the next generation of rehabilitation researchers, graduate students and postdoctoral fellows in biomedical engineering and neuroscience, is ongoing. Physical infrastructure, particularly physical plant has been developed and is in productive use. Other forms of infrastructure such as clinical databases, engineering laboratory facilities, and small equipment have been developed or obtained, and are supporting subsequent funded projects. A large cohort of clinicians and research support staff has been trained and gained experience.

Individual research projects have also been effective. Important findings from the work includes better and faster ways to assess the cognitive and motor status of persons with parkinsonism and traumatic brain injury, randomized controlled trials of treadmill training to restore gait after central nervous system injury, developmental work towards Phase III trials of motor restoration after stroke, and other clinically and scientifically important work. The subsequent federal funding obtained and publications attest to the impact of the NRC, and we anticipate that this growth and development will continue.

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APPENDICES

Project A1: A Computerized Neuropsychological Battery for Parkinson's Disease: Application for Population Surveillance, Early Detection, and Monitoring Disease Progression

Parkinson's Project: Proposed Prototype Tasks

Finger Tapping Task (3 Conditions)

1. Simple Tapping.

Description: Subject is instructed to tap a key as quickly as possible between designated start and stop points. The key pressed could be any key on the keyboard or the mouse button, depending on which of these options provide most accurate timing. This task will consist of several trials (most likely three 20-second trials for each hand).

Symptomatology Targeted: Bradykinesia (slowed movement) and in coordination

Variables Collected:
- o Number of keystrokes within a specified amount of time
- o Number of manual motor blocks (MMBs), defined as situation in which the time between two sequential taps is greater than mean inter-tap interval + 2 SDs
- o Total MMB period as a percentage of total exercise time

2. Paced Rhythmic Tapping.

Description: Subject is instructed to tap a key (or mouse button) in synch with an irregular but repeated rhythm presented either auditorily or visually via the computer. This task will consist of several trials with each hand.

Symptomatology Targeted: Coordination in the presence of an external cue.

Variables Collected:
- o Number of keystrokes within a specified amount of time
- o Percentage of keystrokes that are within a correct window (±20msec?) of external tap
- o Time in msec between each tap
- o Amount of time key is held down for each tap

3. Unpaced Rhythmic Tapping

Description: Subject is presented with the rhythm displayed on the previous condition and then asked to simulate it over several trials without the external pace.

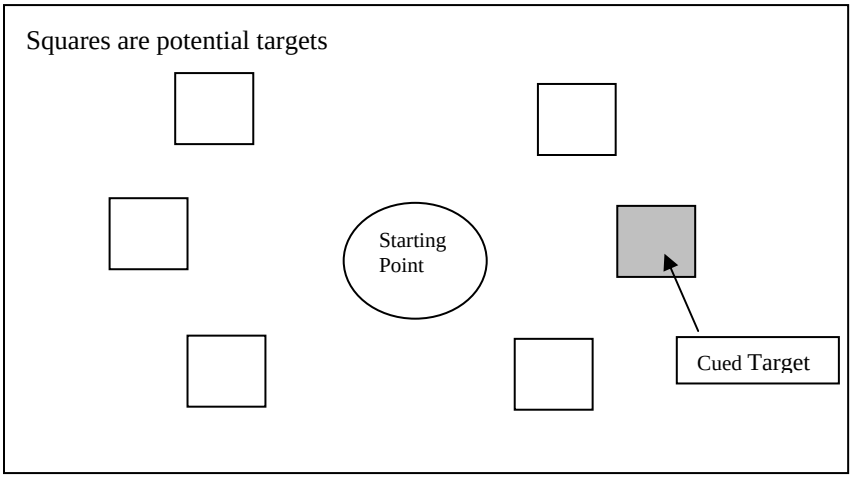
Symptomatology Targeted: Coordination when asked to follow a pattern utilizing only an internal cue.

Variables Collected:

- Number of keystrokes within a specified amount of time
- Time in msec between each tap
- Amount of time key is held down for each tap

Target Acquisition (1 Condition)

Description: Using the mouse, the subject is asked to maintain position on a starting point in the center of the screen. They are told to move as quickly as possible to a specific target when cued. Cued targets will occur randomly on the right or left side of starting point. For example, subject is told to click the square as quickly as possible when it flashes.



Symptomatology Targeted: Bradykinesia, coordination, tremor, poor initiation

Variables Collected:

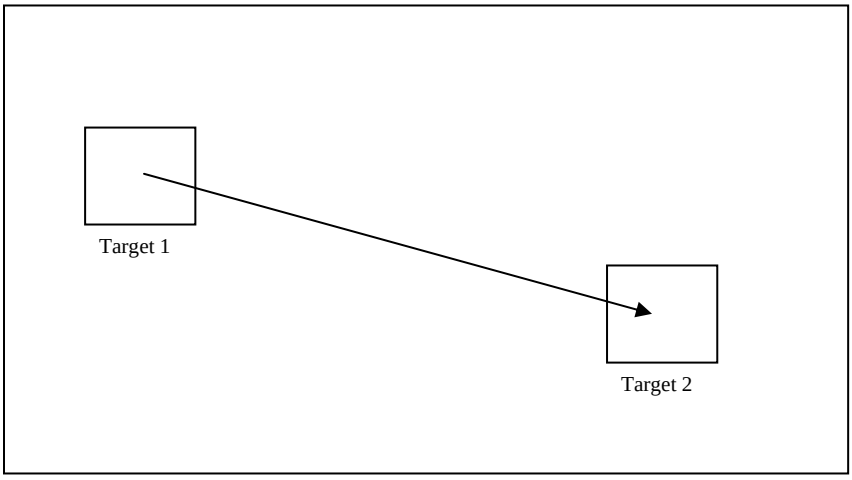
- In order to measure initiation time, will designate a boundary around the starting point. Will measure time between presentation of the cue and time (msec) taken to cross this boundary.
- Reaction time will be designated as time (msec) between presentation of cue and when subject clicks the target (whether correct or incorrect).
- Reaction time for targets presented to the right of starting point. Same for targets to the left.
- Movement time will be total reaction time minus initiation time.
- Percentage of correct responses. Correct response will be those in which subject clicks within a defined boundary of the target.
- Percentage of incorrect responses. Those responses that fall outside of the boundary (measures of coordination).

- o Distance between target and incorrect response for each incorrect trial. Average of these distances will also be calculated.
- o I'd like to include acceleration time for trials to look at consistency but am not sure the best way to do this. For instance, I'd like to be able to differentiate between subjects who smoothly accelerate and select targets between those that reach the target in a "jerky" or "start-stop" manner.
- o I'd like to include some measure of tremor. Possibly by estimating a straight line from start point to target and looking at deviations from this line. Perhaps we could look at area under a curve using actual performance as the curve and a straight line as possible perfect performance.

Alternating Two-Point Target Acquisition (4 Conditions)

1. Two-point target acquisition with fixed targets

Description: Subject is presented with two fixed targets (e.g., two squares) and is told to alternately click as quickly as possible these two targets using the mouse over a period of 60 seconds. Several trials will be presented with only the dominant hand.



Symptomatology Targeted: Bradykinesia, initiation, tremor, and incoordination

Variables Collected:

- o Initiation time for initial start and average initiation over all trials. Variability of inititiation.
- o Average reaction time for all trials (and split out by right to left and left to right movement). Variance of reaction time
- o Movement time (as defined earlier) for initial trial and averaged over all trials. Variance of movement times.
- o Percentage of correct responses. Correct response will be those in which subject clicks within a defined boundary of the target.
- o Percentage of incorrect responses. Those responses that fall outside of the boundary. We should probably separate incorrect responses by incorrect

responses out of sequence by those out of target bounds (measures of coordination).
- o Distance between target and incorrect response for each incorrect trial out of target bounds. Average of these distances will also be calculated.
- o Number of times subject "freezes" on target (stays there > 2 SDs of their own reaction time).
- o Acceleration or average acceleration, as described above.
- o Measure of tremor, as described above.

2. Two-point tapping with moving targets

Description: This task is similar to the above with the exception that the two targets will be moving vertically on the right and left sides of the screen (like pong but the subject is the ball and the targets are the paddles). The subject is told to alternately click as quickly as possible these two targets using the mouse over a period of 60 seconds. Several trials will be presented with only the dominant hand.

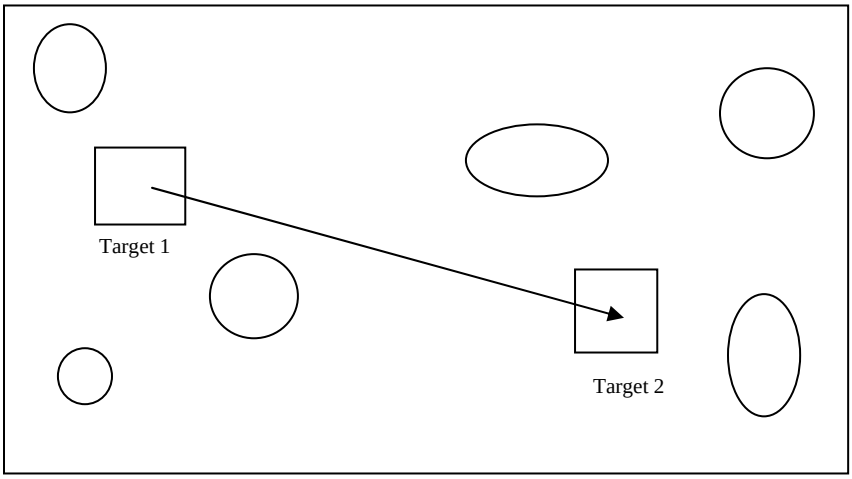
Symptomatology Targeted: Bradykinesia, initiation, and incoordination. This task is intended to be harder than the first to test multiple levels of complexity and potentially elicit symptoms that were not present in the easier version.

Variables Collected:
- o Initiation time for initial start and average initiation over all trials. Variability of initiation.
- o Average reaction time for all trials (and split out by right to left and left to right movement). Variance of reaction time
- o Movement time (as defined earlier) for initial trial and averaged over all trials. Variance of movement times.
- o Percentage of correct responses. Correct response will be those in which subject clicks within a defined boundary of the target.
- o Percentage of incorrect responses. Those responses that fall outside of the boundary. We should probably separate incorrect responses by incorrect responses out of sequence by those out of target bounds (measures of coordination).
- o Distance between target and incorrect response for each incorrect trial out of target bounds. Average of these distances will also be calculated.
- o Number of times subject "freezes" on target (stays there > 2 SDs of their own reaction time).
- o Acceleration or average acceleration, as described above.
- o Measure of tremor, as described above.
- o Measure of tremor, as described above.

3. Two point target acquisition (fixed targets) with distractors

Description: This task is similar to condition one (two target acquisition; targets are stationary) except that now distractors are present. Subjects are presented with two

fixed targets (e.g., two squares) in the midst of other shapes (e.g., circles) and are told to alternately click as quickly as possible these two targets using the mouse over a period of 60 seconds.



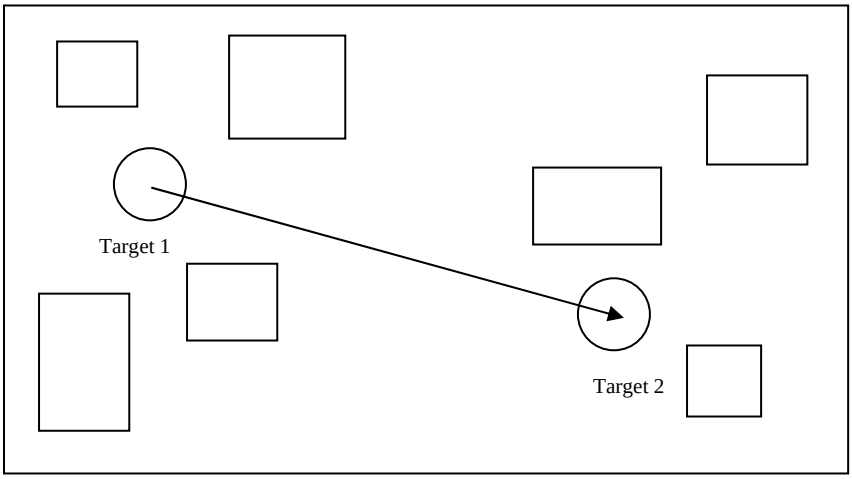
Symptomatology Targeted: Motor symptoms targeted include, bradykinesia, initiation, and incoordination. Cognitive symptoms targeted include, slowed processing speed, slowed visual scanning, and poor selective attention. This task is intended to be harder than earlier conditions to test multiple levels of complexity and potentially elicit symptoms that were not present in the easier version.

Variables Collected:

- Initiation time for initial start and average initiation over all trials. Variability of inititiation.
- Average reaction time for all trials (and split out by right to left and left to right movement). Variance of reaction time
- Movement time (as defined earlier) for initial trial and averaged over all trials. Variance of movement times.
- Percentage of correct responses. Correct response will be those in which subject clicks within a defined boundary of the target.
- Percentage of incorrect responses. Those responses that fall outside of the boundary. We should probably separate incorrect responses by incorrect responses out of sequence by those out of target bounds (measures of coordination).
- Distance between target and incorrect response for each incorrect trial out of target bounds. Average of these distances will also be calculated.
- Number of times subject “freezes” on target (stays there > 2 SDs of their own reaction time).
- Acceleration or average acceleration, as described above.
- Measure of tremor, as described above.

4. Two point fixed target acquisition with changed distractors

Description: This task is similar to condition three except that now the stimuli for targets and distractors are reversed. The two fixed targets are now circles in the midst of squares of varying sizes. Subjects are told to alternately click with the mouse as quickly as possible the two circles (ignoring the squares) over a period of 60 seconds.



Symptomatology Targeted: Motor symptoms targeted include, bradykinesia, initiation, and incoordination. Cognitive symptoms targeted include, slowed processing speed, slowed visual scanning, poor selective attention, and cognitive inflexibility.

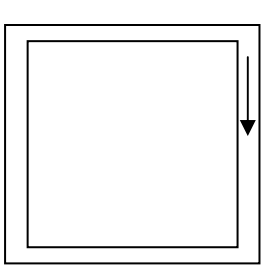
Variables Collected:

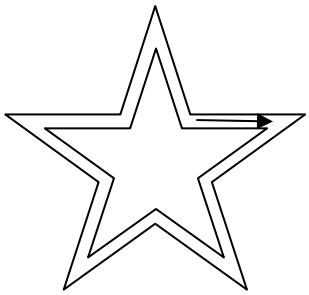
- o Initiation time for initial start and average initiation over all trials. Variability of inititiation.
- o Average reaction time for all trials (and split out by right to left and left to right movement). Variance of reaction time
- o Movement time (as defined earlier) for initial trial and averaged over all trials. Variance of movement times.
- o Percentage of correct responses. Correct response will be those in which subject clicks within a defined boundary of the target.
- o Percentage of incorrect responses. Those responses that fall outside of the boundary. We should probably separate incorrect responses by incorrect responses out of sequence by those out of target bounds (measures of coordination).
- o Distance between target and incorrect response for each incorrect trial out of target bounds. Average of these distances will also be calculated.
- o Number of times subject "freezes" on target (stays there > 2 SDs of their own reaction time).
- o Acceleration or average acceleration, as described above.
- o Measure of tremor, as described above.

Line or Form Tracing (2 Conditions)

1. Form Tracing (Normal Feedback)

Description: For this task the subject is presented with the outlines of a shape and asked to trace the shape without crossing the line. Shapes traced include a circle, square, and star. Subject will be asked to complete each shape several times.





Symptomatology Targeted: Motor symptoms targeted include, bradykinesia, tremor and incoordination. Cognitive abilities targeted include visuomotor integration and procedural learning.

Variables Collected:

- Time (msec) to complete the path.
- Number of times individual makes an error. Errors are defined as deviation from the boundaries of the path
- Magnitude of errors. Summed distance outside of path for all errors.
- Percentage of time person correctly completing path.
- Acceleration or average acceleration, as described above. This should include some measure of freezing behavior.
- Measure of tremor, as described above.
- To measure procedural learning, will calculate percentage change in time to complete for each trial (of same shape). Will also calculate percentage change in total number and magnitude or errors.

2. Form Tracing (Normal Feedback)

Description: This task is similar to condition one; however now the mouse will provide feedback as if the subject is performing in a mirror. That is, when the mouse is moved up, the cursor moves down, etc. The subject will again be asked to trace several forms without crossing the boundaries of the form, each over several trials.

Symptomatology Targeted: Motor symptoms targeted include, bradykinesia, tremor and incoordination. Cognitive abilities targeted include visuomotor integration and procedural learning.

Variables Collected:

- Time (msec) to complete the path.
- Number of times individual makes an error. Errors are defined as deviation from the boundaries of the path
- Magnitude of errors. Summed distance outside of path for all errors.
- Percentage of time person correctly completing path.

- Acceleration or average acceleration, as described above. This should include some measure of freezing behavior.
- Measure of tremor, as described above.
- To measure procedural learning, will calculate percentage change in time to complete for each trial (of same shape). Will also calculate percentage change in total number and magnitude or errors.

Project B2: Gait Restoration in Stroke and Incomplete SCI Patients Using the Lokomat Robotic Treadmill System

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Quantification of functional weakness and abnormal synergy patterns in the lower limb of individuals with chronic stroke

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Abstract

Background: The presence of abnormal muscle activation patterns is a well documented factor limiting the motor rehabilitation of patients following stroke. These abnormal muscle activation patterns, or synergies, have previously been quantified in the upper limbs. Presented here are the lower limb joint torque patterns measured in a standing position of sixteen chronic hemiparetic stroke subjects and sixteen age matched controls used to examine differences in strength and coordination between the two groups.

Methods: With the trunk stabilized, stroke subjects stood on their unaffected leg while their affected foot was attached to a 6-degree of freedom load cell (JR3, Woodland CA) which recorded forces and torques. The subjects were asked to generate a maximum torque about a given joint (hip abduction/adduction; hip, knee, and ankle flexion/extension) and provided feedback of the torque they generated for that primary joint axis. In parallel, EMG data from eight muscle groups were recorded, and secondary torques generated about the adjacent joints were calculated. Differences in mean primary torque, secondary torque, and EMG data were compared using a single factor ANOVA.

Results: The stroke group was significantly weaker in six of the eight directions tested. Analysis of the secondary torques showed that the control and stroke subjects used similar strategies to generate maximum torques during seven of the eight joint movements tested. The only time a different strategy was used was during maximal hip abduction exertions where stroke subjects tended to flex instead of extend their hip, which was consistent with the classically defined "flexion synergy." The EMG data of the stroke group was different than the control group in that there was a strong presence of co-contraction of antagonistic muscle groups, especially during ankle flexion and ankle and knee extension.

Conclusion: The results of this study indicate that in a standing position stroke subjects are significantly weaker in their affected leg when compared to age-matched controls, yet showed little evidence of the classic lower-limb abnormal synergy patterns previously reported. The findings here suggest that the primary contributor to isometric lower limb motor deficits in chronic stroke subjects is weakness.

Background

Muscle weakness, or the inability to generate normal levels of force, has clinically been recognized as one of the limiting factors in the motor rehabilitation of patients following stroke [1,2]. In the lower limbs, this muscle weakness can be attributed to disuse atrophy [3] and/or the disruption in descending neural pathways leading to inadequate recruitment of motorneuron pools [1,4-6]. It has also been reported that weakness following stroke may be the result of co-contraction of antagonistic muscles [7-9]. Spasticity has also been proposed as an alternative explanation for lower limb impairments in hemiparetic stroke [10,11], but more recent studies have found that spasticity may not play a significant role in gait abnormalities [12,13].

A well documented factor limiting the motor rehabilitation of patients following stroke is the presence of abnormal muscle activation patterns. Following stroke, some patients lose independent control over select muscle groups, resulting in coupled joint movements that are often inappropriate for the desired task [14,15]. These coupled movements are known as synergies and, for the lower limb, have been grouped into the extension synergy (internal rotation, adduction, and extension of the hip, extension of the knee and extension and inversion of the ankle) and the flexion synergy (external rotation, abduction, and flexion of the hip, flexion of the knee, and flexion and eversion of the ankle) [16,17] with varying levels of completeness [18] and dominance [19].

Much of the literature attempting to quantify these abnormal muscle synergies is focused on the paretic upper limb of stroke patients. In isometric conditions, it has been shown that stroke patients have a limited number of upper limb synergies available to them due to abnormal muscle coactivation patterns [20]. In dynamic tasks, abnormal synergy patterns exist in the paretic upper limb between shoulder abduction with elbow flexion as well as shoulder adduction with elbow extension [21]. These, and other inappropriate upper limb muscle synergy patterns were attributed to abnormal torque generation about joints secondary to the intended, or primary, joint axis during maximal voluntary isometric contractions [22].

This analysis technique of quantifying torques at joints secondary to the intended joint axis was applied to the lower limbs of cerebral palsy patients in a seated position, where abnormal secondary joint torques were expressed during maximal hip and knee extension [23]. However, it has been shown that gravity can influence the control of limb movements by affecting sensory input [24] and altering task mechanics [25,26]. When acute (<6 weeks post-injury) stroke subjects were placed in a functionally relevant weight-bearing anti-gravity standing position, no such abnormal secondary joint torque patterns during maximal voluntary isometric contractions were found, even though primary joint torques deficits were observed [27].

The goal of this study was to quantify lower limb weakness and coordination in chronic (> 1 year post-injury) stroke patients in a functionally relevant standing position. Subjects were asked to generate maximum isometric contractions about a given joint while torques at joints secondary to the desired exertion were simultaneously calculated and recorded. This allowed us to quantify weakness as a torque deficit and coordination as the generation of any synergy patterns in the lower limbs of hemiparetic stroke patients. Additionally, EMG activity of relevant muscles was simultaneously recorded to quantify the presence of abnormal muscle activation patterns.

Methods

Subjects

Sixteen subjects (9 male, 7 female) with hemiparesis resulting from a single unilateral cortical or sub-cortical brain lesion at least one year prior to testing participated in this study along with sixteen (9 male, 7 female) neurologically intact age-matched controls. Subjects were excluded from the study if they were too severely impaired to voluntarily move about the ankle, knee, and hip joints, measured by a Fugl-Meyer lower limb score below 10 out of 34. Subjects with a Fugl-Meyer lower limb score greater than 30 out of 34 were deemed very highly functional and excluded. The synergy control sub-score of the Fugl-Meyer assessment was also used to characterize subjects. This clinical score (0–22) reflects the ability to move within (0–14), to combine (15–18), or to move out of (19–22) classically defined dynamic synergy patterns. Although some subjects scored high on the Fugl-Meyer lower limb and synergy control sub-score, all subjects exhibited difficulty in walking typical of hemiplegic stroke subjects. Subjects were also screened for cognitive and communication impairments and only those with Mini Mental State Examination scores greater or equal to 22 were tested. All subjects were excluded for any uncontrolled cardiovascular, neurological, or orthopaedic conditions, such as high blood pressure, arthritis, or history of seizure, that would inhibit exercise in a standing position. Informed consent was obtained before testing and all protocols were approved by the local institutional review boards. The clinical characteristics of each subject group is shown in Table 1.

Instrumentation

Each subject was placed in a custom setup that allowed for the study of strength and coordination of the lower extremities in a standing posture (Figure 1). The subject's

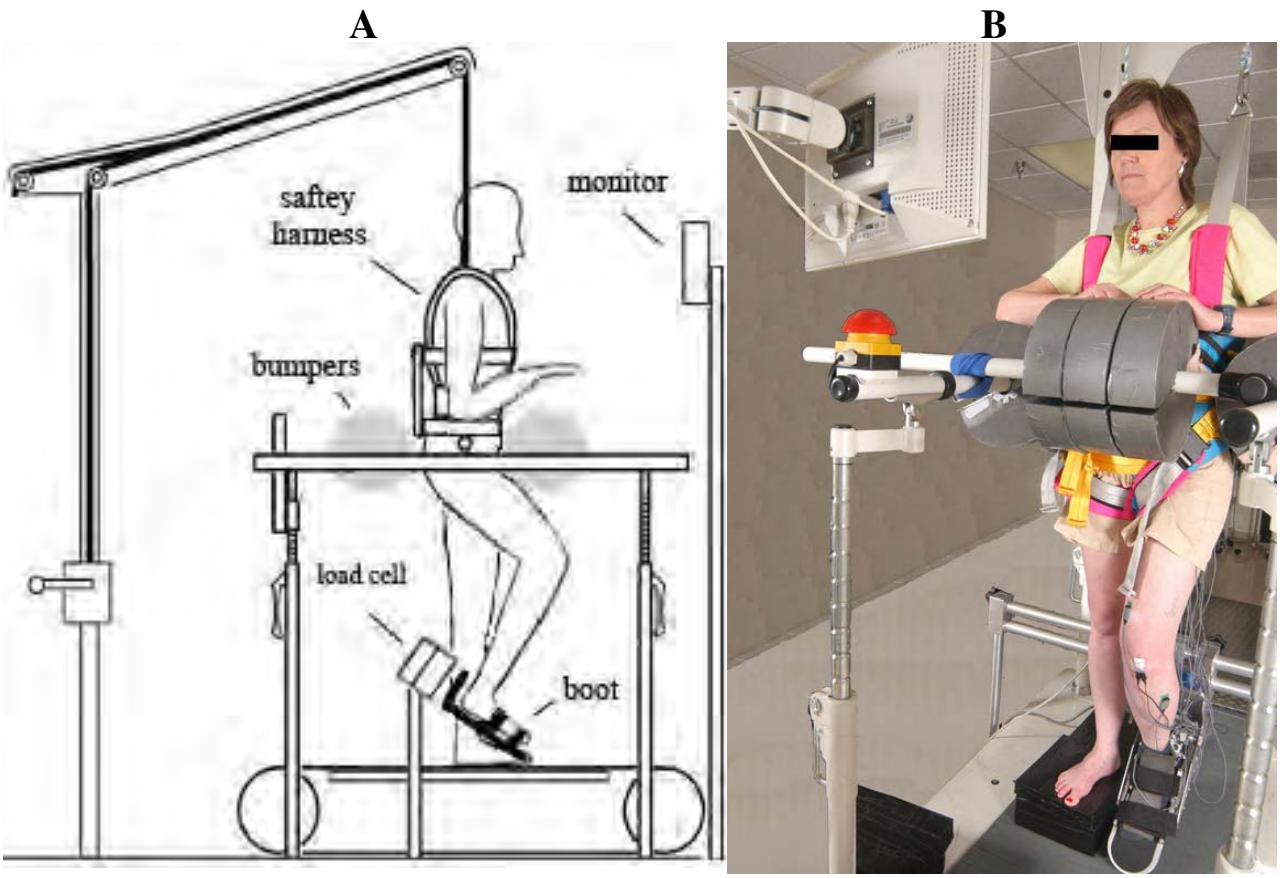

Figure 1
Experimental Set-up. **A.** Subjects were secured in a standing position with foam bumpers pinching the hips from four sides and a safety harness prevented subjects from slipping down. The subject's foot was attached to a boot that was fixed to a six DOF load cell that would measure joint torques about the hip, knee and ankle. A monitor provided feedback on the torque generated in the primary joint direction. EMG activity was recorded from eight muscles. **B**. Photograph of experimental setup.

affected foot was securely placed inside a custom foot retainer which in turn was connected to a 6-axis load cell (JR3, Woodland CA). The foot retainer was angled down 30 degrees with respect to the horizontal so that all subjects had an ankle angle of 100 degrees and a knee angle of 135 degrees. Large foam bumpers were used to support the subject's trunk during the exertions. Because the tests were done with the subject in a standing posture, a harness was placed around the subject's abdomen and attached to an over-head body-weight support system in order to prevent falls. No support was provided by the system during the tests. Some subjects did, however, sit down in the harness between trials to rest their support leg. Additionally, a heart rate monitor was placed around the subject's chest which was repeatedly checked during testing by a physical therapist to ensure the exertions did not elevate the subject's heart rate to unsafe levels. A monitor for biofeedback was placed in front of the subjects to reinforce exertions along each joint axis.

Electromyographic (EMG) recordings were collected using a Bagnoli-8 EMG system (Delsys, Inc., Boston, MA) with surface electrodes placed above the muscle belly's of the tibilias anterior, gastrocnemius, biceps femoris, vastus medialis, rectus femoris, gluteus maximus, gluteus medius, and adductor longus, and a common reference electrode placed on the patella. Electrode sites were abraded with a rough sponge and cleaned with isopropyl alcohol. The Ag-AgCl electrodes (contact dimension 10 mm × 1 mm, contact spacing 10 mm) were prepped with adhesive stickers and electrode gel. The preamplifiers provided a gain of ×10+-2%, the amplifiers a gain selectable from ×100 to ×10,000 with a bandwidth of 20–450 Hz.

The common mode rejection ratio was >80 dB at 60 Hz and the input impedance was $>10^{15}$//0.2 ohm//pF.

EMG data, along with the forces and torques from the load cell, were anti-alias filtered at 500 Hz prior to sampling at 1000 Hz using a 16-bit data acquisition board (Measurement Computing, PCI-DAS 6402, Middleboro, MA) and custom data acquisition software written in Matlab (Mathworks Inc. Natick, MA) and stored for later analysis.

Protocol

Subjects were asked to generate maximum voluntary torques (MVTs) about eight different joint directions (ankle, knee, and hip flexion and extension, as well as hip abduction and adduction). For each joint direction, the subject was allowed to practice until they understood the task, after which three trials were recorded. Subjects were watched closely to make sure that they maintained their legs in the proper geometry. Trials were discarded and recollected if subjects attempted to change leg geometry in order to achieve maximum torques. A minimum of one minute rest period was given between each trial. The subjects would start in a relaxed state and slowly ramp up to a maximum which was held for approximately 4 seconds. Visual feedback of the torque generated only along the desired direction was provided by a speedometer style display on the monitor. The order of joint movements was selected to minimize subject fatigue (hip adduction, knee flexion, hip extension, ankle flexion, hip abduction, knee extension, hip flexion, ankle extension). All subjects followed the same order of selected joint torques. Verbal encouragement and instructions were provided throughout the experiment.

Data analysis

For each trial the MVT, or primary torque, as well as the three secondary torques were measured along with the EMG data from the eight selected muscles. The different joint torques were computed by taking the forces and torques measured by the load cell (denoted frame {o}) and transforming them back to the different joints using a homogeneous transformation matrix [28]. From the load cell, ankle torques can be calculated from:

$$\begin{bmatrix} F_a \\ T_a \end{bmatrix} = \begin{bmatrix} {}^a_0R & 0_{3\times3} \\ {}^aP_o \times {}^a_oR & {}^a_oR \end{bmatrix} \begin{bmatrix} F_o \\ T_o \end{bmatrix} \qquad (1)$$

where ${}^a_oR$ is a 3 × 3 rotation matrix from {o} to {a}, ${}^aP_o \times {}^a_oR$ is a 3 × 3 skew matrix from {o} to {a}, and F_i and T_i denote force and torque in each respective frame.

Ankle forces and moments can then be transformed back to the knee as:

Table 1: Clinical Characteristics of Subjects

Group	Gender	Age (years)	Paretic Leg Tested	Months Post-Stroke	Synergy Control (max. = 22)	Fugl-Meyer Score %
Stroke Survivors	F	30	R	39	13	79
	F	36	R	26	21	88
	F	48	R	13	21	68
	F	51	L	54	21	91
	F	53	L	36	6	53
	F	57	L	26	20	53
	F	64	R	14.5	9	88
	M	44	R	149	17	71
	M	50	R	194	16	53
	M	50	R	29	14	56
	M	55	R	34	10	68
	M	56	R	30	15	47
	M	59	L	13.5	16	44
	M	63	L	23	11	47
	M	68	L	20	19	47
	M	69	R	18.5	11	76
Stroke Average	9 male 7 female	53.31 (+/-10.68)	10 right leg 6 left leg	44.97 (51.18)	15 (4.72)	64.34 (16.46)
Control Average	9 male 7 female	57.13 (+/-8.85)	10 right leg 6 left leg	/	/	/

Standard Deviation in parenthesis

$$\begin{bmatrix} F_k \\ T_k \end{bmatrix} = \begin{bmatrix} {}^k_a R & 0_{3\times3} \\ {}^k P_a \times {}^k_a R & {}^k_a R \end{bmatrix} \begin{bmatrix} F_a \\ T_a \end{bmatrix} \quad (2)$$

And from the knee to hip as:

$$\begin{bmatrix} F_h \\ T_h \end{bmatrix} = \begin{bmatrix} {}^h_k R & 0_{3\times3} \\ {}^h P_k \times {}^h_k R & {}^h_k R \end{bmatrix} \begin{bmatrix} F_k \\ T_k \end{bmatrix} \quad (3)$$

The skew and rotation matrices are formed from anatomical measurements while the subject is in the setup (shank and thigh lengths, knee and shank angles).

A MVT was defined as the peak torque sustained for 200 ms observed across any one of the 3 trials for that primary joint direction. The corresponding secondary torques exerted along the other joint axes during the 200 ms MVT window were also identified. For example, during maximum voluntary knee flexion exertions, secondary torques consisted of those generated along the ankle flexion-extension axis, hip flexion-extension axis, and hip abduction-adduction axis. Secondary torques generated during all trials were normalized to the MVT measured for that particular joint direction. Cases where a secondary torque exceeded 100% MVT indicated that the subject generated less torque while attempting to maximize that particular direction than when they were trying to maximize a different direction.

The EMG activity from the eight selected muscle groups was band-pass filtered (20–450 Hz), full-wave rectified, and then smoothed using a 200-point RMS algorithm. Each EMG trace was then normalized to the maximum EMG value observed across all trials for the respective muscle. This allowed for muscle activity demonstrated during the 200 ms MVT window to be expressed as the percentage of peak activity observed in each muscle.

Statistical analysis

A single factor ANOVA was used to compare the means of the chronic stroke subjects to the control subjects for each of the eight primary joint torque directions. A single factor ANOVA was used to compare the mean secondary torques, as well as the mean EMGs, between the stroke and control groups. An independent Student's *t*-test was used to identify secondary torques that were significantly greater than zero ($P < 0.05$). Correlations (Pearson's, 2-tailed) between joint torque were found by grouping all data from the eight primary torque directions and comparing all instances of one torque direction with the activity at the other three joints. For example, all instances of hip abduction were compared with the torques of the hip, knee and ankle, regardless if it was flexion or extension. Statistical analyses was performed with the software package SPSS (SPSS Inc, Chicago, IL) and a confidence level of 0.05 was used for all comparisons.

The role of co-activation of antagonistic muscles on observed joint weakness was investigated by computing a co-contraction index (*CI*) for each primary torque direction as follows:

$$CI = \frac{\sum PCSA_i * EMG_{agonist,i}}{\sum PCSA_j * EMG_{antagonist,j}} \quad (4)$$

where *PCSA* is the physiological cross sectional area of the healthy adult muscle [29]. The total activity demonstrated in the agonist muscle groups divided by the total muscle activity demonstrated in the antagonistic muscle groups results in the CI for that primary torque direction. One or more of the eight muscles recorded from were regarded as agonist/antagonist muscles for each primary torque direction (ankle flexor – tibilias anterior, ankle extensor – gastrocnemius, knee flexors – gastrocnemius and biceps femoris, knee extensors – vastus medialis and rectus femoris, hip flexor – rectus femoris and adductor longus, hip extensors – gluteus maximus and biceps femoris, hip abductor – gluteus medius, hip adductor – adductor longus and gluteus maximus). It was important to scale the muscle activity by the PCSA since activity in large muscle groups generated significantly higher forces than activity in muscles with smaller cross-sectional area. The CI is a simple numerical measure of how much co-activation of antagonistic muscle groups subjects exhibit. Low CI occurs when subjects simultaneously activate agonist and antagonist muscle groups, whereas high CI is indicative of low levels of co-contraction. High levels of co-contraction (Low CI) would result in decreasing levels of torque exerted at the joint. A single factor ANOVA test was used to compare the mean CI values of the chronic stroke subjects to the control subjects with a significance level of $p < 0.05$.

Results

Maximum voluntary torque

The maximum voluntary primary torques for the eight joint directions are shown in figure 2. The stroke group was significantly weaker ($p < 0.05$) for all joint directions except for knee extension and hip flexion. The average stroke hip flexion torque was less than the control group, but with a higher variability. The average stroke knee extension torque was actually larger than the control group, but again, with a higher variability.

Secondary torque and EMG patterns

Figures 3 through 6 show the normalized secondary torque patterns as well as the normalized EMG activity for all control subjects and all but one stroke subject during

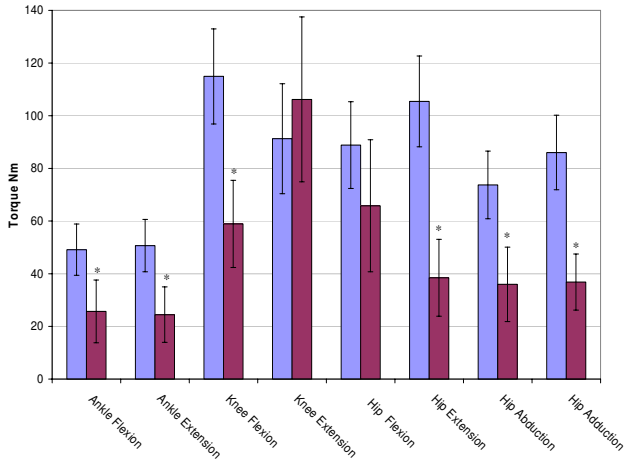

Figure 2
Maximum Voluntary Torques. The maximum voluntary joint torques for the stroke (red) and control (blue) groups expressed in Newton meters for the eight primary directions ankle flexion through hip adduction. Error bars represent 95% confidence interval. Significant differences ($p < 0.05$) are denoted *.

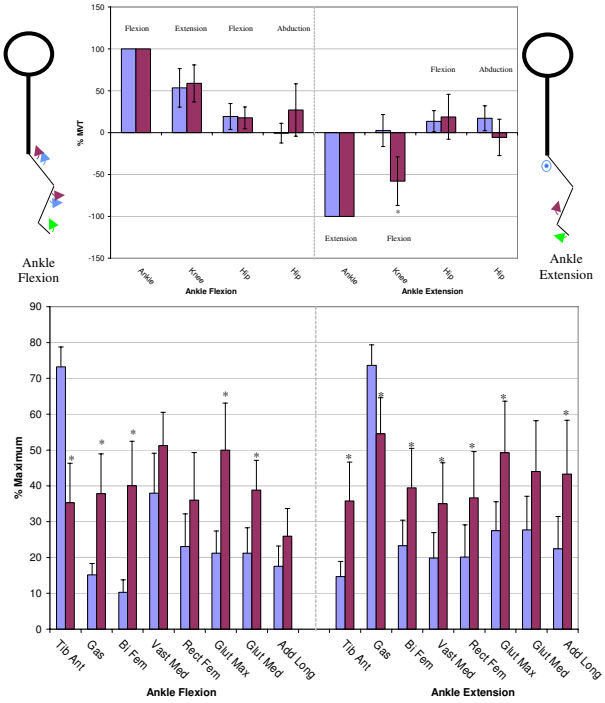

Figure 3
Secondary Torques During Ankle Flexion/Extension. The top graphs show the secondary joint torques for the stroke (red) and control (blue) groups expressed in %MVT for ankle flexion (left) and ankle extension (right). The stick figures show the primary joint direction (green) as well as the secondary torques of the control (blue) and stroke (red) for the secondary joint torques that are significantly greater than zero. Abduction is denoted as a circled dot (out of the page), adduction is denoted a circled X (into the page). The bottom graph shows the EMG activity for the stroke (red) and control (blue) groups expressed in % maximum value during ankle flexion MVT (left) and ankle extension MVT (right). Error bars represent 95% confidence interval. Significant differences between groups ($p < 0.05$) are denoted *. Tib Ant – tibilias anterior, Gas – gastrocnemius, Bi Fem – biceps femoris, Vast Med – vastus medialis, Rect Fem – rectus femoris, Glut Max -gluteus maximus, Glut Med – gluteus medius, Add Long – adductor longus.

the eight different primary directions. EMG data for one stroke subject was improperly collected and has hence been omitted. The stick figure diagrams illustrate the secondary torque generation that was significantly greater than zero ($P < 0.05$). A more detailed discussion of the different joint directions is presented below.

Ankle flexion/extension

As illustrated in Figure 3, during ankle flexion, both controls and stroke subjects generated knee extension and hip flexion secondary torques. While generating maximal ankle flexion, the stroke subjects had significantly less tibilias anterior activity but significantly greater gastrocnemius, biceps femoris, gluteus maximus, and gluteus medius activity. During maximal ankle extension exertions, the stroke subjects generated a knee flexion secondary torque that was significantly higher than the control subjects ($p < 0.05$). The EMG pattern on the right side of figure 3 shows that the stroke subjects had significantly less gastrocnemius muscle activity and significantly greater tibilias anterior, biceps femoris, vastus medialis, rectus femoris, gluteus maximus, and adductor longus muscle activity during maximal ankle extension exertions.

Knee flexion/extension

During maximal knee flexion exertions, both groups generated ankle extension, hip extension and hip adduction secondary torques that were not different from each other (Figure 4). Interestingly, the stroke subjects had significantly greater gluteus maximus, and gluteus medius activity during maximum knee flexion exertions despite the fact that they did not produce larger hip extension secondary torque. For knee extension, both groups produced ankle flexion, hip flexion and hip abduction secondary torques however the ankle flexion secondary torque was significantly larger in the stroke group, and significantly greater than 100%. The hip flexion secondary torque was also greater than 100% in the control group but not significantly different than the stroke group. The EMG pattern illustrates that the stroke group had a greater gastrocnemius and biceps femoris activity during knee extension MVT.

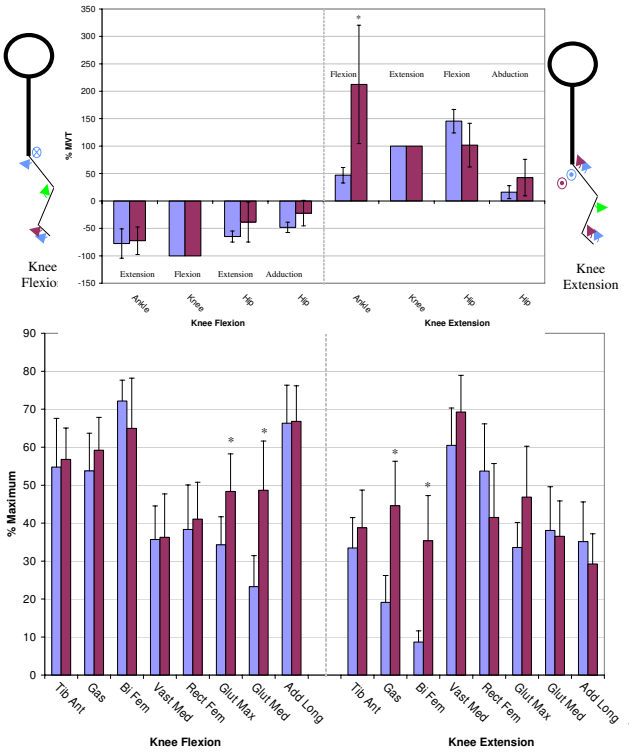

Figure 4
Secondary Torques During Knee Flexion/Extension. The top graphs show the secondary joint torques for the stroke (red) and control (blue) groups expressed in %MVT for knee flexion (left) and knee extension (right). The stick figures show the primary joint direction (green) as well as the secondary torques of the control (blue) and stroke (red) for the secondary joint torques that are significantly greater than zero. Abduction is denoted as a circled dot (out of the page), adduction is denoted a circled X (into the page). The bottom graph shows the EMG activity for the stroke (red) and control (blue) groups expressed in % maximum value during knee flexion MVT (left) and knee extension MVT (right). Error bars represent 95% confidence interval. Significant differences between groups ($p < 0.05$) are denoted *. Tib Ant – tibilias anterior, Gas – gastrocnemius, Bi Fem – biceps femoris, Vast Med – vastus medialis, Rect Fem – rectus femoris, Glut Max -gluteus maximus, Glut Med – gluteus medius, Add Long – adductor longus.

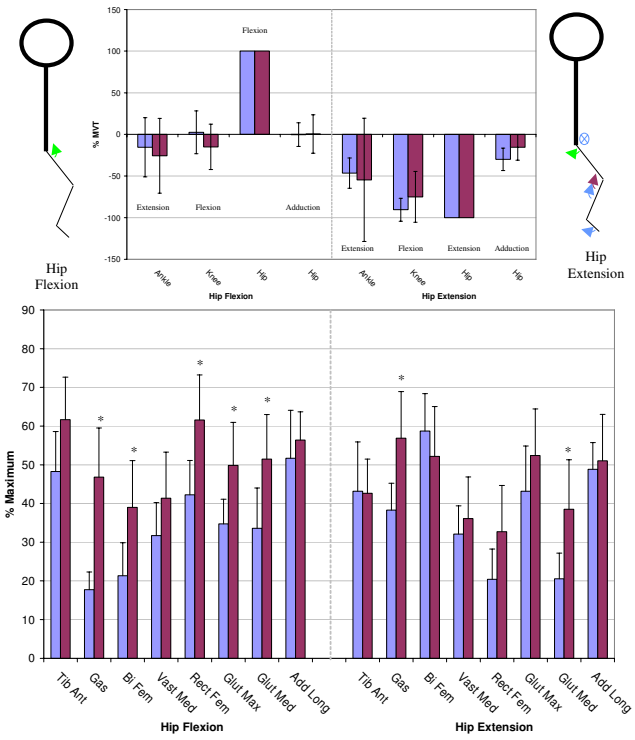

Figure 5
Secondary Torques During Hip Flexion/Extension. The top graphs show the secondary joint torques for the stroke (red) and control (blue) groups expressed in %MVT for hip flexion (left) and hip extension (right). The stick figures show the primary joint direction (green) as well as the secondary torques of the control (blue) and stroke (red) for the secondary joint torques that are significantly greater than zero. Abduction is denoted as a circled dot (out of the page), adduction is denoted a circled X (into the page). The bottom graph shows the EMG activity for the stroke (red) and control (blue) groups expressed in % maximum value during hip flexion MVT (left) and hip extension MVT (right). Error bars represent 95% confidence interval. Significant differences between groups ($p < 0.05$) are denoted *. Tib Ant – tibilias anterior, Gas – gastrocnemius, Bi Fem – biceps femoris, Vast Med – vastus medialis, Rect Fem – rectus femoris, Glut Max - gluteus maximus, Glut Med – gluteus medius, Add Long – adductor longus.

Hip flexion/extension

Figure 5 illustrates the secondary torques generated during hip flexion, where it can be seen that neither group generated significant secondary torques. However the stroke group produced greater activity in the gastrocnemius, biceps femoris, rectus femoris, gluteus maximus, and gluteus medius muscles. During hip extension MVT, both groups produced a secondary knee flexion torque and the control group produced additional ankle extension and hip adduction secondary torques that were not significantly different from the stroke. The EMG pattern in figure 5 shows that the stroke group had greater gastrocnemius and gluteus medius activity during hip extension MVT.

Hip abduction/adduction

During hip abduction, the control group produced a hip extension secondary torque while the stroke group produced a hip flexion secondary torque, the difference being significantly different (Figure 6). During hip abduction MVT, the stroke subjects had significantly greater gastroc-

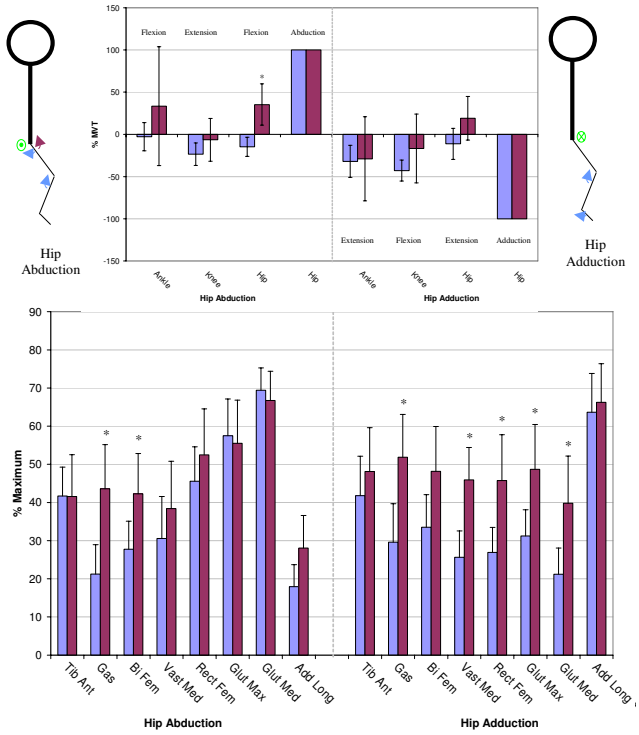

Figure 6

Secondary Torques During Hip Abduction/Adduction. The top graphs show the secondary joint torques for the stroke (red) and control (blue) groups expressed in %MVT for hip abduction (left) and hip adduction (right). The stick figures show the primary joint direction (green) as well as the secondary torques of the control (blue) and stroke (red) for the secondary joint torques that are significantly greater than zero. Abduction is denoted as a circled dot (out of the page), adduction is denoted a circled X (into the page). The bottom graph shows the EMG activity for the stroke (red) and control (blue) groups expressed in % maximum value during hip abduction MVT (left) and hip adduction MVT (right). Error bars represent 95% confidence interval. Significant differences between groups ($p < 0.05$) are denoted *. Tib Ant – tibilias anterior, Gas – gastrocnemius, Bi Fem – biceps femoris, Vast Med – vastus medialis, Rect Fem – rectus femoris, Glut Max -gluteus maximus, Glut Med – gluteus medius, Add Long – adductor longus.

nemius and biceps femoris activity than the control subjects. For hip adduction MVT, none of the secondary torques were significantly different. The EMG pattern on the right side of figure 6 illustrates how the stroke group had greater gastrocnemius, vastus medialis, rectus femoris, gluteus maximus, and gluteus medius activity than the control subjects during hip adduction MVT.

Summary of secondary torques

For each group the secondary torques significantly greater than zero for the eight primary joint directions (figures 3 through 6) are summarized in Table 2. For each primary joint direction listed on the left, the secondary torques significantly greater than zero are marked with an 'X'. Additionally, significant correlations ($p < 0.05$) between joint torques within each group are marked with an 'O'. To find these correlations all instances (primary or secondary) of a torque were pooled and compared to the other three joint torques. For example, all trials where ankle flexion was present were pooled and ankle flexion was compared to knee flexion/extension, hip flexion/extension, and hip abduction/adduction. The arrangement of rows and columns in Table 2 leads to the grouping of the primary joint directions into synergies. These synergies are based on the direction of the moment arm of the joint torque in the sagittal plane. Ankle flexion, knee extension, and hip flexion secondary torques are grouped as the Anterior Synergy while ankle extension, knee flexion, and hip extension are grouped as the Posterior Synergy. The frontal plane joint torques of hip abduction and adduction are differently grouped. Hip adduction is part of the posterior synergy in the control group but not part of any synergy in the stroke group. Hip abduction is part of the anterior synergy in the stroke group but part of the posterior synergy in the control group.

Co-contraction index

Figure 7 shows the co-contraction index for the eight primary torque directions. The stroke group produced a significantly lower index, and thus greater co-contraction of antagonistic muscle groups during ankle flexion, ankle extension and knee extension. This was especially true during ankle extension where the stroke subjects exerted significantly higher tibialis anterior activity than the control subjects.

Discussion

Primary joint torques

As expected, stroke subjects were weaker than age-matched controls for ankle flexion and extension, hip extension, abduction and adduction, and knee flexion. Surprisingly there were no significant differences in hip flexion and knee extension. Even more surprising was that the stroke subjects were, on average, stronger than the control group in knee extension. Median analysis confirms that this is not just the result of a few exceptional stroke subjects. The median stroke knee extension torque was 90.60 Nm while the median control knee extension torque was 81.01 Nm. A closer inspection of the stroke subjects that generated large knee extension or hip flexion torques reveals that these stroke subjects were only stronger in one joint direction, and often generated below average MVT in the other joint directions tested. It is not unreasonable for an ambulatory, active stroke subject to use knee extension as part of a compensatory strategy, and

Table 2: Secondary Torque Synergies

	Control	Ankle Flexion	Knee Extension	Hip Flexion	Hip Abduction	Hip Adduction	Ankle Extension	Knee Flexion	Hip Extension
Primary Torque	Ankle Flexion		X	X					
	Knee Extension	X O		X O	X				
	Hip Flexion		O						
	Hip Abduction							X O	X O
	Hip Adduction						X O	X O	O
	Ankle Extension				X				
	Knee Flexion					X O	X O		X O
	Hip Extension					X O	X O	X O	
	Stroke								
	Ankle Flexion		X O	X O					
	Knee Extension	X O		X O	X				
	Hip Flexion	O			O				
	Hip Abduction	O	O	X O					
	Hip Adduction								
	Ankle Extension							X	
	Knee Flexion						X O		O
	Hip Extension						O	X O	
			Anterior Synergy					Posterior Synergy	

over time, have it be as strong, or stronger, than an age-matched control.

Other factors influencing MVT, such as age, sex, or time post stroke were checked, but no significant correlation was found. However such conclusions are somewhat limited due to our sample size.

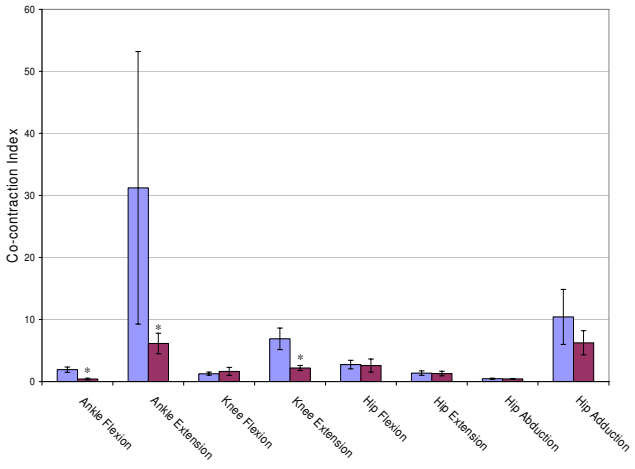

Figure 7
Co-contraction Index. Cocontraction index for the eight primary joint torques. Larger values represent lower levels of cocontraction. Error bars represent 95% confidence interval. Significant differences between groups ($p < 0.05$) are denoted *.

Secondary joint torque patterns

Abnormal coordination patterns in the upper limbs of hemiparetic stroke subjects have been quantified as the generation of torque in joints secondary to the primary joint axis [22]. When this analysis of secondary joint torques was applied to the lower limbs of cerebral palsy subjects, abnormal secondary torques were produced at the hip and knee [23] which were consistent with the classically defined extension synergy [15,16,30]. Presented here is evidence that such classically defined extension and flexion synergy patterns are not present in the lower limbs of chronic stroke subjects while in a functionally relevant standing, weight bearing position.

Torque patterns of healthy subjects

When asked to generate MVTs along the hip, knee, and ankle flexion and extension axes, the healthy control subjects produced secondary torques in the directions that were consistent with both the mechanical demands of the task and the physical properties of the musculature of the legs. For instance, when asked to generate a maximum knee extension torque, healthy subjects produced secondary hip and ankle flexion torques. So the presence of positive secondary torques of hip and ankle flexion are consistent with mechanical demands of the task. Not surprisingly healthy subjects had a high level of rectus femo-

ris activity during knee extension MVT. The rectus femoris is known as both a knee extensor and hip flexor so the generation of secondary hip flexion during knee extension is consistent with the physical properties of the leg musculature. This led to the grouping of the sagittal plane torques into two synergies. The posterior synergy consisted of hip extension, knee flexion, and ankle extension while the anterior synergy consisted of hip flexion, knee extension, and ankle flexion.

When asked to generate MVTs in the frontal plane joint directions of hip abduction and adduction, healthy subjects produced secondary torques that were not necessarily consistent with the physical properties of the musculature of the legs. The adductor longus is known as a hip flexor as well as adductor, but during high levels of adductor longus activity there was no production of significant hip flexion torque. However, the lower fibers of the gluteus maximus are known to adduct the hip [31] and during high gluteus maximus activity, there were significant secondary hip adduction torques. To further classify the torque patterns of healthy subjects in the frontal plane (joint exertions of hip abduction and adduction) a summary chart of significant secondary torques and correlated joint moments was constructed. Table 2 shows that hip adduction torque was correlated to knee flexion torque (marked 'O'), whereas hip adduction secondary torques were present during knee flexion and hip extension MVTs (marked 'X'). This led to classifying hip adduction as part of the posterior synergy. Even though hip abduction secondary torques were produced during a MVT of an anterior synergy component (knee extension) it has been classified as part of the posterior synergy because hip abduction torque was correlated to knee flexion and hip extension. The presence of hip abduction secondary torques during ankle extension MVT further justifies the posterior synergy classification.

Torque patterns of chronic stroke subjects

During MVTs in the sagittal plane, chronic stroke subjects showed no evidence of the classic extensor and flexor synergies and behaved similarly to the healthy subjects. The torque patterns of the chronic stroke subjects differed from the healthy subjects only during hip abduction MVT. While healthy subjects produced significant hip extension torques, chronic stroke subjects produced significant hip flexion torque. This abnormal coupling of hip abduction and hip flexion is consistent with the classically defined flexion synergy.

A closer investigation into the secondary torque patterns generated during knee extension revealed that secondary torques were sometimes larger than the torques generated voluntarily. While we cannot conclude this origin for certain, we postulate that a strategy used to generate a MVT may unknowingly involve certain levels of co-contraction that would reduce the net torque. That is, it could be that the agonist muscles may be more active and the antagonistic muscles more relaxed during a strategy used to generate a MVT about a different joint. This would result in a net secondary torque that is larger than a net primary torque. This is not too unusual in the case of chronic stroke subjects generating secondary ankle flexion moments twice as large as their voluntary maximums. The majority of the stroke subjects had poor control at their ankle and often struggled to produce substantial ankle flexion torque. However while concentrating on knee extension exertions, any small increase in a synergistic ankle flexion exertions would be a rather large percentage. The slight increase in tibilias anterior activity from 35.32 % maximum during ankle flexion MVT to 38.78% maximum during knee extension MVT further supports this. Unfortunately this phenomena gets a little more unusual when the levels of co-contraction are compared. A recalculation of ankle co-contraction index during knee extension MVT generation shows that there is a similar amount of co-contraction about the ankle during both voluntary ankle flexion (0.393 +/- 0.279 stdv) and voluntary knee extension (0.396 +/- 0.378 stdv), although recordings of the superficial leg muscles were made. It is likely that had more muscles been recorded from (e.g. soleus) a better understanding for the observed behavior could be explained.

The interesting finding that in control subjects, hip flexion secondary torques were greater than 100% MVT might be explained by the activity of the rectus femoris. During hip flexion MVT control subjects seamed to rely on moderate levels of both rectus femoris (42% maximum) and adductor longus (52% maximum) to achieve hip flexion torques. But during knee extension MVT the rectus femoris activity of the control subjects was higher (54% maximum). A recalculation of hip co-contraction index during knee extension MVT shows that there is less co-contraction about the hip during voluntary knee extension (3.58 +/- 1.39 stdv) than during voluntary hip flexion (2.73 +/- 0.68 stdv). However these findings are not significantly different and had more muscles been recorded from a better understanding for the observed behavior could be explained.

Weakness in chronic stroke

In a functionally relevant standing position, chronic stroke subjects produced significantly lower torques in six of the eight joint directions tested. Weakness in stroke has been attributed to inadequate recruitment of motorneuron pools [1,4,6] spasticity [10,11], disuse atrophy [3] and the co-contraction of antagonists [7-9]. In an attempt to quantify the amount of co-contraction during the generation of MVTs a co-contraction index was calculated. The

chronic stroke subjects produced significantly more co-contraction during ankle flexion and ankle extension which may partially explain the joint torque deficits in those directions. But the stroke subjects produced significantly more co-contraction during knee extension even though they produced a similar level of torque. While inadequate recruitment of motorneuron pools can not be ruled out, it does appear that the co-contraction of antagonistic muscle groups may at least contribute to the observed weakness in the chronic stroke subjects tested. This is consistent with our previous work that demonstrated significant co-activation of antagonistic muscle groups in acute stroke subjects [27].

Conclusion

Presented here for the first time is a quantitative analysis of lower limb weakness and synergy patterns of chronic stroke subjects in a functionally relevant standing weight-bearing position. In a standing position with added vestibular inputs, stroke subjects showed little evidence of the classic abnormal synergy patterns in seven of the eight directions tested. The findings here suggest that the primary contributor to lower limb motor deficits in chronic stroke subjects is weakness, which is at least partially due to co-contraction of antagonistic muscles.

Declaration of competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

NN carried out the experiments, collected and analyzed the data, and drafted the manuscript. MP prepared subjects and assisted with the experiments. DN prepared subjects and assisted with the experiments. JH designed the experiment, developed data collection software, and helped draft the manuscript. All authors read, edited, and approved the final manuscript.

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Advances in the Understanding and Treatment of Stroke Impairment Using Robotic Devices

Joseph Hidler, Diane Nichols, Marlena Pelliccio, and Kathy Brady

The presence of robotic devices in rehabilitation centers is now becoming commonplace across the world, challenging heath care professionals to rethink treatment strategies for motor impairment in hemiparetic stroke patients. In this article, we will discuss some of the motivations for using these devices, review clinical outcomes following robotic-assisted training in both the upper and lower extremities, and detail how these devices can provide quantitative evaluations of function. We will also address the clinical issues that need to be considered when using robotic devices to treat stroke patients, and finally a vision of where this field is heading will be discussed. **Key words:** *gait, stroke, rehabilitation, robotics*

Over the last decade, the integration of robotic devices into neurorehabilitation centers across the world has reshaped clinical strategies when considering treatment options for individuals with motor impairments resulting from neurological injuries. What began as proof-of-concept testing in the 1990s has evolved into widespread acceptance among many researchers and clinicians. Today, robotic devices are being used as rehabilitative tools for treating physical impairments in both the upper and lower limbs. Because these devices have precise instrumentation that measures variables such as position and forces, they are also being used to diagnose and assess motor impairments such as spasticity, tone, and strength with great accuracy. Because they are driven with mechanical motors, these devices can automate repetitive tasks such as passive ranging, active reaching, and gait training in time-unlimited durations. Furthermore, in instances where more than one therapist is necessary to provide a therapeutic intervention, such as gait training a severely impaired acute stroke patient, robotic devices may also help reduce health care costs. It must be emphasized that the goal of introducing rehabilitation robots into clinics is not to replace physical and occupational therapists, but rather robots are a complement to existing treatment options.

Although there are numerous potential benefits to adopting these technologies into the rehabilitation setting, there are also some potential drawbacks, including safety, clinician and patient acceptance, and the ability to bill for time on these devices. Because rehabilitation robots come with state-of-the-art technology, the up-front costs can be overwhelming for smaller centers.

In this review article, we will discuss some of the key findings and contemporary issues surrounding the introduction of robotic devices into

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neurorehabilitation programs targeting hemiparetic stroke patients. First, the motivation and potential benefits of using rehabilitation robotics will be discussed. Then, clinical outcomes following robotic training programs will be presented and interpreted for both the upper and lower extremities. Next, we will discuss how these devices can be used as diagnostic tools that provide quantitative evaluations of function. A discussion of the clinical considerations that need to be taken into account when using robotic devices to treat stroke patients will be outlined, and finally a vision of where this field is heading will be proposed.

Motivation

The idea of massed-practice therapy is not a new concept in the world of rehabilitation professionals; it is used in various forms throughout occupational and physical therapy. One obvious limitation with this type of intervention from a health care cost perspective is that it is often quite labor intensive, requiring one-on-one therapist–patient interactions for highly impaired individuals. For example, manual-assisted gait training often requires multiple therapists, and even then it places excessive physical demands on the therapists that sometimes result in repetitive strain injuries, lower back problems, and extreme fatigue. It would be difficult if not impossible for even the most proficient and skilled therapist to maintain high-quality therapy across a full case load of patients who require this type of attention.

One of the main motivations for developing rehabilitation devices is to automate or assist interventions that normally require multiple therapists or that are extremely physically demanding. For example, during reach-to-grasp tasks, the robot can provide visual cues to the patient and then assist the movement if they are unable to complete the task.[1] As the patient regains function, the robot can make the task more challenging by adding resistance during the movements or perhaps adding obstacles the patient must navigate through or avoid. Because the movements are guided by an actuated device, the number of reaches is not limited in time or duration.

Another potential benefit of integrating these devices into rehabilitation clinics is that rehabilitation robots are able to accurately measure and track the patient's impairments over the course of a therapeutic intervention. Clinical scales such as FIM™,[2*] Ashworth,[3] and others are subjective and often suffer from poor interrater reliability.[4] Robotic devices can monitor or measure numerous behaviors within a session and across sessions, making it possible for the therapist to track improvements and also justify their time to health care providers and payers.

There is little doubt that our population is aging; it is projected that the size of the elderly population (those 65 years or older) will rise from approximately 33+ million (12.7% of US population in 1999) to 53 million in 2020 and 77 million by 2040.[5] From a health care cost perspective, this trend is troubling because, after the age of 55, the probability of suffering a stroke doubles with each decade,[6] and more than half of all stroke survivors are left with some long-term disability.[6] In parallel, economic pressures are forcing rehabilitation centers to treat patients in shorter periods of time. Often patients are discharged while they are continuing to make functional gains. Because the duration of inpatient stays at rehabilitation hospitals is decreasing and the number of outpatient therapy sessions is being continuously reduced, it is imperative to optimize the therapy patients are able to receive in the limited time window available to our clinicians and therapists.

Robot Therapy Clinical Outcomes

Since the concept of using robotic devices to deliver goal-directed physical therapy was first explored through a number of small controlled studies in the mid 1990s,[7,8] dozens of trials have been conducted in both the upper and lower limbs. Here, we present summaries of both upper and lower limb studies that have looked at the effectiveness of robotic rehabilitation in facilitating the restoration of function in hemiparetic stroke survivors (see also refs. 9, 10, and 11 for reviews).

*FIM™ is a trademark of the Uniform Data System for Medical Rehabilitation, a divison of UB Foundation Activities, Inc.

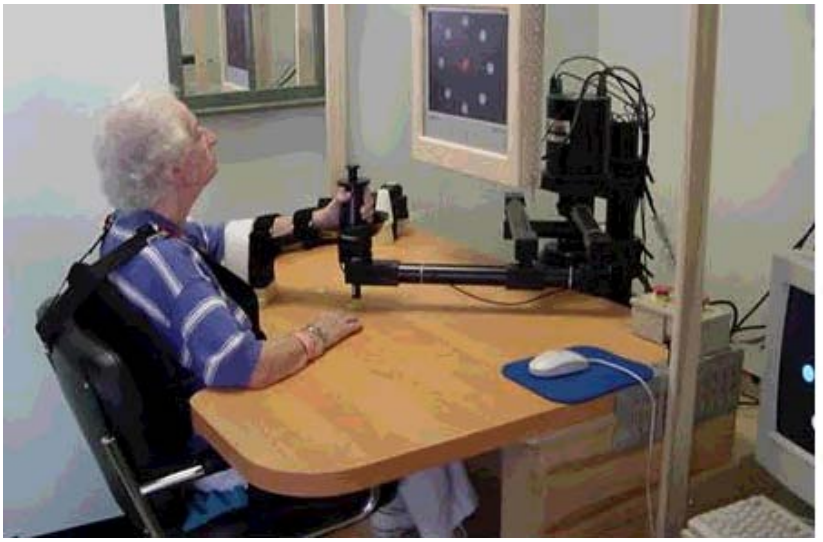

Figure 1. MIT-MANUS (Interactive Motion Technologies, Cambridge, MA).

Upper limb robotic rehabilitation

Although there have been numerous devices designed to deliver arm therapy in individuals with neurological injuries, we highlight three that have undergone extensive testing with hemiparetic stroke subjects: MIT-MANUS,[8,12,13] ARM-GUIDE,[14] and MIME.[15,16]

MIT-MANUS

The MIT-MANUS was developed at the Massachusetts Institute of Technology in the early 1990s[12] with the goal of determining whether repetitive reaching exercises using a robotic device can enhance recovery of the arm function in hemiparetic stroke survivors. The MANUS, as shown in Figure 1, allows subjects to execute reaching movements in the horizontal plane. During movements, the device can assist or resist the subject and monitor arm position and applied forces. The manner in which the MANUS interacts with the subject is intended to be safe, stable, and compliant throughout the training paradigm.

A collection of cumulative studies utilizing the MIT-MANUS have been published for acute[8,13,17–19] hemiparetic stroke subjects with the goal of determining whether subjects who receive robotic-assisted arm therapy coincident with their conventional therapy make greater improvements in upper limb function than those who receive "sham" robot therapy along with their conventional therapy. In each of these studies, the robot-trained subjects used the MANUS to reach toward various targets across their workspace; if they were unable to complete the movement, the robot assisted them. On average, three packets of 20 repetitions were done with the impaired limb, totaling 4–5 hours per week over a 7-week period. The sham group received 1 hour of additional therapy per week, where they used the device for 30 minutes with their unimpaired arm and the other 30 minutes with their impaired arm. The motors on the MANUS were not turned on so that if these subjects did not complete their intended movement, they used their unaffected limb to assist the affected limb complete the task.

Evaluation of upper limb motor impairment and ability to carry out functional tasks was done before and after the intervention and included the FIM[2]; subset of the upper limb Fugl-Meyer (FM) functional impairment scale[20]; strength in the biceps, triceps, anterior, and posterior deltoid muscles using the Medical Research Council Motor Power (MP) scale; and Motor Status Score (MSS) for the shoulder-elbow complex (MSS-SE) and wrist-hand complex (MSS-WH).[21]

After testing 96 acute stroke subjects (average of 2

weeks post stroke at enrollment) at the Burke Rehabilitation Hospital (White Plains, NY) through a double-blinded study, it was found that the robot-trained group demonstrated significantly greater gains in elbow and shoulder motor function (MSS-SE, $p < .001$) and elbow and shoulder strength (MP, $p < .005$) than the sham control group. No significant differences were between groups were observed in Fugl-Meyer scores at the shoulder, elbow, wrist, or hand nor were there differences in FIM or motor function (MSS-WH) at the wrist and hand. A 3-year follow-up study evaluating 12 of the first 20 subjects enrolled in the study found that there were no significant differences in any of the outcome measures described earlier except for shoulder-elbow motor status score (MSS-SE, $p < .05$).

Recent studies have explored the idea of using the MIT-MANUS in chronic subjects[22,23] and have found similar trends. That is, even in the chronic stages of their injury, subjects are able to improve shoulder and elbow function after training for 6 weeks with the robot. Furthermore, these gains were sustainable for at least 4 months, which suggests that long-term improvements in function are achievable even in the chronic stages of stroke.

Even though these studies demonstrate functional improvements in both acute and chronic stroke subjects following training on the MIT-MANUS arm robot, a few points of contention need to be raised. First, in the acute studies presented here, the control group only received 1 hour of extra therapy per week while the robot-trained group received approximately 5 hours. Of this 1 hour of therapy, 30 minutes were spent training the unimpaired arm. So it is questionable whether true comparisons should be drawn between the two types of interventions. Furthermore, Volpe et al.[18] noted that the control group had significantly lower FIM motor and cognitive scores, and, while not statistically significant, there was a trend for the lesion volumes to be larger in the control group than in the robot-trained group. Each of these issues may raise questions about whether robot therapy with the MIT-MANUS is more effective than conventional therapy, but there is little doubt that the robot-trained group demonstrated statistically significant gains in function after repeated sessions with the device.

ARM-GUIDE

One possible limitation with the MIT-MANUS is that it emphasizes training within the horizontal plane. Subjects who trained on the MANUS did demonstrate improvements in shoulder strength and function, but some researchers have hypothesized that training in a three-dimensional workspace may enhance these functional gains. Reinkensmeyer et al.[14,24,25] developed a trombone-like device called the Assisted Rehabilitation and Measurement Guide (ARM-GUIDE) that allows stroke subjects to reach along a rail, which in turn can be positioned so that the subjects' reaching motion can be neutral to gravity or can work against gravity (Figure 2). Like the MIT-MANUS, the device is actuated with a motor that can assist or resist the subject's motion and is also instrumented to monitor hand position and speed. A 6-degree of freedom force sensor is mounted just below the handle so that forces exerted by the subject along the rail and also orthogonal to the desired motion can be quantified. The device can be adjusted in the elevation and yaw axes, and the extent of the movement can also be controlled. The device continues to be used as both a diagnostic tool (see the section, "Robot Therapy Clinical Outcomes") and a treatment tool for addressing arm impairment in hemiparetic stroke subjects.

A small controlled study was carried out that compared long-term arm training on the ARM-GUIDE to a control group that executed free-reaching movements.[26] In this study, a group of chronic stroke subjects (more than 1-year post stroke) were trained; six subjects used the ARM-GUIDE and four acted as controls. The ARM-GUIDE group reached toward targets arranged across their reaching workspace with their impaired arm. In this setting, the ARM-GUIDE was pointed toward the selected target; after receiving a visual cue, the subject was instructed to try and reach toward the target as fast as possible. If the hand velocity of the subject followed a predetermined hand trajectory, then the motor on the ARM-GUIDE provided no assistance. However, if the subject reached either too fast or too slow, the device resisted or assisted the movement, respectively. In this setting, the subjects' goal was to

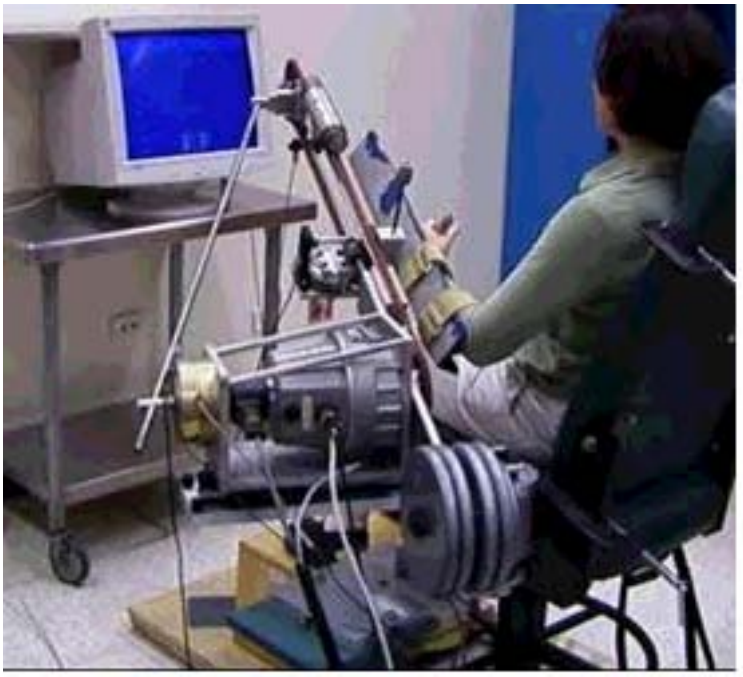

Figure 2. Assisted Rehabilitation and Measurement Guide (ARM-GUIDE).

follow a prescribed velocity path that spanned their range of motion. Graphical feedback of their hand position was provided during each reach.

The control group executed free reaching toward targets arranged on a wall that were similar in direction as the targets used in the ARM-GUIDE group. Here, the subjects were not constrained to move along any path; they were simply asked to reach toward the various targets at a comfortable speed. Each trial began with the hand of their impaired arm resting on their lap. A Flock of Birds (Ascension Technology Corporation, Milton, VT) sensor was placed on the back of the subjects' hand to monitor their reach trajectory. Visual feedback was also provided to this group after they completed a sequence of reaches.

Both groups were trained 3 days per week for 8 weeks, totaling 24 sessions. Evaluations of performance were done prior to and following training using the Chedoke-McMaster Upper Extremity Stroke Assessment Scale[27] for monitoring arm function and the Rancho Los Amigos Test[28] for evaluating each subject's ability to carryout everyday tasks. Subjects also carried out passive and active tests on the ARM-GUIDE to measure passive limb mechanics and voluntary reach range and speed.

It was found that both subject groups improved in the Chedoke-McMaster and Rancho Los Amigos Tests; however, there were no statistical differences between the improvements across groups. Furthermore, both groups demonstrated statistically significant improvements in active range of reach and reaching speed and demonstrated decreased passive resistance to movement ($p < .05$). However again, there were no statistical differences between groups, which indicated that both therapeutic interventions had similar effects.

While this study only consisted of 10 chronic stroke subjects, it raises questions about whether it is the mode of therapy or the amount of therapy that is ultimately important in restoring arm function to hemiparetic stroke subjects. It should be noted that the starting impairment level in the ARM-GUIDE group was slightly greater than that of the control subjects, which may slightly skew the results. However, it appears from this study that the results can be interpreted in at least two ways: robotic-assisted therapy is no more effective than conventional therapy, or the type of robotic-

Figure 3. Mirror Image Movement Enabler (MIME).

assisted therapy used in this study is not optimal for addressing arm impairment in this patient population. This group is currently exploring a variation of the ARM-GUIDE protocol to try and address this issue.[29]

MIME

The final upper limb training protocol based on robotic-assisted movements that will be discussed was designed through a collaborative effort between the Veteran Administration Medical Center in Palo Alto and Stanford University and is called MIME (Mirror-Image Movement Enabler).[1,15] The robot utilized in this protocol, a PUMA 560 industrial device (Staubli Corporation, Duncan, SC), was modified so that it could interact with subjects in a stable and repeatable manner. The subject's impaired limb was placed in a splint, which in turn was connected to the robot through a 6-degree of freedom force-torque sensor (Figure 3). This sensor is able to measure the interaction forces between the subject and the device during reaching tasks. The device is fully instrumented so that the position of the subject's limb can be inferred through the robot's position. The idea behind this protocol was to explore the effectiveness of restoring arm function in stroke subjects by having them execute movements that mirror one another in both of their upper limbs.

In these studies, four different modes of operation were explored. In the first mode, the subject's arm was passively moved by the robot from a starting position to a target along some predetermined kinematic trajectory. During these movements, the subject was asked to relax the paretic limb and allow the device to passively move the arm. In the second mode of therapy, the subject would attempt to move to a target while the robot would stabilize the limb. The subject was only allowed to move in the direction of the target and not back toward the starting position. If the subject attempted to move toward the target and could not make it, the robot would support the limb and assist the movement. In the third mode of operation, the robot was programmed to provide some viscous resistance as the subject reached for the targets across the workspace. Finally, the fourth mode of training was developed to be bimanual in nature, where the subject would reach for symmetric targets using both arms at the same time, one connected to the robot and the other connected to a position-sensing digitizer. Here, the motion of the unimpaired forearm dictated the range and rate of the movements of the impaired arm that was assisted by the robot. The idea was that in the bimanual mode the subject had full control over the path and rate of movements of both arms.

To evaluate the effects of these robot modes of therapy in comparison to NeuroDevelopmental

Therapy (NDT), 27 chronic stroke subject (more than 6 months post stroke) were tested, where each subject received 24 one-hour sessions over a 2-month period.[11] For the robot group, subjects practiced shoulder and elbow movements that were assisted by the robot. Here, targets were placed away from the subject so that the emphasis was placed on reaching movements to various points in the workspace. All subjects spent approximately 12 minutes in bimanual mode, 5 minutes in passive mode, and the remainder of the session in practicing active-assisted or active-resisted modes depending on their functional level. For the control group, subjects were trained using NDT; the subjects practiced various tasks with their arm that focused on functional or self-care tasks.

Evaluations of intervention effects were done at months 0, 1, and 2 and at a 6-month follow-up session and included Fugl-Meyer testing,[20] Barthel Index,[30] FIM,[2] and maximum strength testing under isometric conditions. Evaluation of active reach was also examined by having the subject make reaches to targets positioned at various places in a three-dimensional space, during which arm position and orientation were quantified using a lightweight, instrumented forearm splint.

Following 24 sessions of training, it was found that the subjects who received MIME therapy made statistically higher gains in proximal arm function (Fugl-Meyer scores), strength (elbow extension, shoulder flexion, and shoulder abduction and adduction), and the amount of active reach. The robot group made statistically faster gains in proximal arm function during the 2 months of training; however, at the 6-month follow-up, there were no statistical differences in function between the two groups. No changes were found between subjects in distal arm function or ability to perform activities of daily living (ADLs; Barthel Index or FIM).

In a similar study that only focused on subjects trained using the MIME protocol,[16] it was found that the amount of work the subjects were able to perform during active reaches had significantly increased. In subjects with low levels of function, the extent of reach had improved; in high-functioning subjects, the movement velocity was significantly higher. Improvements in elbow and shoulder muscle activation patterns were also observed in subjects who performed reaches against gravity, but no improvements were noted during table-top movements.

Preliminary summary: arm devices

This study, like the MIT-MANUS study, provides evidence that training with a robotic device can improve arm function in hemiparetic stroke subjects, but it is task specific. That is, both of these studies found that proximal arm function improved more rapidly and to a greater extent in the robot group, however distal arm function did not experience these same gains. Both devices used in these studies emphasize proximal tasks, so it is not surprising that changes in wrist and hand function were no different from those in the control groups.

What is somewhat disappointing in these studies is that subjects experienced improvements in function according to scales such as Fugl-Meyer and Motor Status Score, but changes in the subjects' ability to perform ADLs were no greater in the robot-trained group than they were in the control groups. One has to consider which aspect of recovery is more important to the consumer; the ability to perform things at home that would make them more independent or tests that are supposed to be indicative of their ability to perform ADLs. We postulate that future studies using these and other robotic devices must demonstrate clear benefits to the subjects' ability to perform ADLs, otherwise acceptance of these devices by the clinical community and the consumer will be significantly compromised.

Lower limb robotic rehabilitation

The concept of body weight–supported locomotor training is now being used extensively in most neurorehabilitation centers and is demonstrating promising results. Over the last 10 years, it has been shown that subjects who receive body weight–supported treadmill training after spinal cord injury [31–33] and stroke[34–36] demonstrate improved EMG activation patterns,[31,37] more natural walking characteristics,[35] are able to bear more weight on their legs,[32] and demonstrate functional

Figure 4. Lokomat gait orthosis (Hocoma AG, Volketswil, Switzerland).

improvement in walking ability.[33,37] Furthermore, there are also reports of reductions in spasticity[33] and increases in cardiopulmonary efficiency[38] after body weight–supported locomotor training.

The major drawback of manual-assisted locomotor training is that it places large physical demands on the therapists, which limits the consistency and duration of training sessions. Furthermore, from a health care cost basis, manual-assisted locomotor training is quite expensive, as it often requires multiple therapists to properly administer. To address these limitations, a number of robotic gait trainers have been developed, all having the goal of delivering time-unlimited, consistent gait training in individuals with neurological injuries. We highlight two such devices that are currently being used in various clinics around the world: the Lokomat[39] and the Gait Trainer.[40]

Lokomat gait orthosis

The Lokomat robotic gait orthosis has been in development since the mid 1990s in order to automate the delivery of locomotor training for individuals with neurological injuries.[39] This system is comprised of a treadmill, a body weight–support system, and two lightweight robotic arms that attach to the subject's legs (Figure 4). The Lokomat is fully programmable, including control of knee and hip kinematic trajectories, the amount of assistance the system provides to the

subject, and the speed at which the subject ambulates. This high-level dynamic control is achieved by small direct current (DC) motors and linear ball screw assemblies at the hip and knee joints that are tightly synchronized with the timing of the treadmill. Hip and knee angles are monitored through high-precision potentiometers while dorsiflexion is provided at the ankle of the subject through two passive elastic straps. Unloading of the patient is achieved by connecting the shoulder straps on a harness to a counterweight system. Furthermore, force sensors mounted in series with the motors sense the amount of resistance/assistance the subject is generating while walking in the device, which can be used as biofeedback for motivational purposes. The Lokomat is an FDA-approved medical device.

Because the Lokomat has only been commercially available since 2002 (Hocoma AG, Volketswil, Switzerland), no large-scale studies have been published comparing the effects of Lokomat gait training to conventional gait training in hemiparetic stroke subjects. A multicenter study currently being conducted by the National Rehabilitation Hospital and the Rehabilitation Institute of Chicago is investigating this question in subacute stroke subjects (less than 6 months post stroke), where it is anticipated that the results of more than 100 participants will be reported in the fall of 2007. That study is being sponsored by the National Institute on Disability and Rehabilitation Research (NIDRR) under Rehabilitation Engineering Research Center (RERC) "Machines Assisting Recovery from Stroke (MARS)."

Mechanized Gait Trainer

Another robotic device that targets gait training in stroke subjects is the Gait Trainer[40,41] developed in Germany, which works very similarly to traditional elliptical trainers. In this setting, the subject's feet are strapped to two footplates, which in turn are connected to a linkage system that moves the foot through a trajectory quasi-similar to the gait cycle. The foot is always connected to the platforms, and the positioning and loading of the foot on the Gait Trainer is comparable to the stance and swing phases of the gait cycle, with a ratio of 60% and 40% for each phase, respectively. The stride length and phase durations can be adjusted by using different gear ratios on the linkage system, while the step velocity is modulated between 0 to 1.12 m/s. Furthermore, the linkages connected to the footplates are connected to a motor that can provide varying levels of assistance throughout the gait cycle, ranging from full support when the subject provides no assistance to little or no support when the subject actively propels his or her legs. Similar to the Lokomat, the forces generated by the subject can be used as biofeedback during training.

A randomized crossover design was performed to evaluate the effectiveness of using the mechanized Gait Trainer in a group of nonambulatory stroke subjects (n = 30; 4–12 weeks poststroke).[36] Subjects enrolled in the study were randomly assigned to one of two groups: a group that received treatments A-B-A and a group that received treatments B-A-B. Intervention A consisted of 15–20 minutes of daily locomotor training on the Gait Trainer for 2 weeks; intervention B consisted of the same doses of therapy only on the treadmill. In the robot and treadmill interventions, a portion of the subject's body weight was supported using an overhead unloading system. Furthermore, assistance with weight shifts and leg kinematics (e.g., foot placement and knee control) was provided by a therapist in both groups as required for each subject. Evaluations of walking ability consisted of the Functional Ambulation Category (FAC),[42] gait velocity, and Rivermead Motor Assessment Score,[43] and ankle spasticity was quantified using the modified Ashworth scale.[3] Assessments were performed by an independent evaluator blinded to the subject's treatment group before training, weekly, and finally at a 6-month follow-up visit.

After 6 weeks of therapy, both the A-B-A group and B-A-B group demonstrated improvements in walking ability (FAC), walking speed, and Rivermead scores. FAC scores were found to be statistically higher in the A-B-A group than the B-A-B group, however there were no group differences in walking speed or Rivermead scores. No changes in ankle spasticity were found in either group. By the 6-month follow-up evaluation, none of the outcome measures were statistically different across groups.

For the robot intervention, therapy sessions

could be carried out by one therapist even in highly impaired subjects; whereas for the treadmill training intervention, sometimes three therapists were needed to properly train low-functioning subjects. This likely cost productivity highlights one of the benefits of robotic rehabilitation, particularly with the current health care economic pressures.

A potential limitation with the Gait Trainer is that the system does not directly control the knee or hip joints nor is the trunk supported. In acute stroke subjects, weakness across the knee and hip joints often results in poor joint stability, so that hyperextension may occur unless otherwise controlled by a therapist or trainer. Furthermore, because the subject's feet are always attached to the pedals, unnatural cutaneous inputs to the bottom of the feet may alter sensory inputs normally experienced during gait. Nevertheless, the outcomes of this study provide promising indications that robotic-assisted gait training may result in positive returns in walking ability.

Preliminary summary: gait training devices

Although there are limited experimental results supporting the effectiveness of robotic-assisted devices in restoring walking function in hemiparetic stroke subjects, the need for gait-specific devices is of high importance because training subjects with significant motor impairment is labor intensive and often requires multiple therapists. If devices such as the Lokomat or Gait Trainer can replicate results in neurological subjects that are similar to the results experienced after manual-assisted locomotor training, the cost benefits of robotic devices may ultimately help facilitate their adoption into rehabilitation centers.

Quantifying Impairment Using Robotic Devices

The section "Robot Therapy Clinical Outcomes" highlighted various studies of the effectiveness of robotic devices as therapeutic tools for upper and lower limb rehabilitation, but these devices are also well-suited to quantify motor function and impairments in hemiparetic stroke subjects. Because all of the devices discussed previously are fully instrumented with sensors that measure limb position, velocities, and forces, these variables can be used to study impairment with a high degree of precision. Furthermore, this information can also be used to track recovery and perhaps even dose therapy. By better understanding the mechanisms underlying impairment, more effective treatments may ultimately be developed. In this section, we discuss a few examples of robotic devices used to evaluate arm and leg function in hemiparetic stroke survivors.

Previously, we highlighted the MIT-MANUS (Figure 1) as a therapeutic tool for aiding in the recovery of arm function in stroke subjects. The MIT-MANUS has also been used to track changes in smoothness during arm movements[8,44] and the ability to execute continuous arm movements.[45] Both of these characteristics, smoothness and continuity, are inherent characteristics of coordinated human movement.[46] In these studies, stroke subjects were instructed to either make point-to-point linear movements or draw a circle. The resulting hand movements were examined for the number of corrective movements made, the shape of the velocity profile, and other metrics of smoothness. It was found that throughout the course of recovery, stroke subjects demonstrate improvements in their ability to execute smooth, continuous movements that are similar to nonneurologically impaired subjects. For example, Krebs et al.[8] showed that prior to robot training, when subjects attempted to draw circles, the shape of the circle was highly distorted and a large number of corrective movements were made. However, through the progression of the intervention, the shape of each movement became more circular and the velocity profile began resembling a bell-shape with less corrective movements, both being normal characteristics.

Reinkensmeyer et al.[24,25] utilized the ARM-GUIDE (Figure 2) to study active and passive restraints exhibited by chronic stroke subjects during guided reaching. Subjects were instructed to reach as far and as fast as possible along the guide and to try not to push up or down or left or right against the device. The arm was also moved through the entire range of motion by the device while the subject relaxed in order to evaluate passive tissue properties. It was found that during ac-

tive reaches subjects generate large and significant forces against the rail perpendicular to the desired movement. These forces were consistent with the synergy patterns previously reported in chronic stroke subjects.[47,48] Furthermore, it was found that passive tissue constraints were significantly higher in the impaired arm and that deficits in active reach extent were attributable to spasticity and weakness. These studies demonstrate the utility of robotic devices to investigate the mechanisms underlying arm dysfunction in stroke subjects.

Techniques are also being developed to evaluate walking ability and gait impairments using robotic devices.[49] The goal of this work is to establish the optimal set of training parameters, such as walking speed and level of body weight support, for maximizing the effectiveness of the therapy. A standard Lokomat (Figure 4) has been modified in two distinct ways. First, the cuffs that couple the subject's legs to the Lokomat have been customized to contain 6-degree of freedom load sensors that allow for the accurate measurement of the assistance or resistance the device provides the subject. Second, a split belt treadmill that resides under the Lokomat contains sensors that allow for the calculation of ground reaction forces and centers of pressure. Utilizing the leg–Lokomat interaction forces, the ground reaction forces, and the kinematic data (e.g., position and velocity of the legs), a modified inverse-dynamics technique is used to estimate the ankle, knee, and hip moments the subject generates under any set of training parameters. Combining this information with electromyographic (EMG) information, the role of impairments such as weakness, spasticity, and abnormal synergies on walking ability can be studied, and the set of training parameters through which the subject steps to generate the best joint moments and muscle activation patterns can be identified. The goal is to train subjects under conditions that may lead to higher returns in walking ability after long-term locomotor training.

Clinical Considerations When Incorporating Robotic Devices into Rehabilitation Centers

A major consideration of most facilities with regard to using robotics will be the cost effectiveness of treatment. The purchase of robotic systems such as the Lokomat or MIT-MANUS presents a significant expense for any clinical facility. There are numerous administrative costs related to clinical use of the robotic as well. Therapists and aides must be trained to use the equipment safely and effectively; this is nonreimbursable time for the department. Training not only involves learning how to properly set-up the patients into the device but also gaining a detailed understanding of both the hardware and software that accompany the robot. Once the proper fit has been determined, an aide might be able to perform any necessary set-up of the robot prior to the patient getting into the robotic system, but the therapist should check the set-up before any training begins.

Unlike most physical therapy settings where a therapist might see more than one patient at a time, robotic training currently requires one-on-one treatment. While this may soon change for some devices (see the section, "Future Directions"), currently group therapy with these devices is not possible and therefore impacts department revenue. In some robotic devices, particularly the gait trainers, an additional person in the lab is often necessary for efficiency and safety purposes. For example, due to co-morbidities in the patient populations using the Lokomat (typically SCI, CVA, and TBI), blood pressure, cardiac, or diabetic issues can arise during training sessions. Although training can be accomplished safely with one person, it often requires a minimum of two people to get a patient safely out of the device when time is critical. With the proven benefit of robotics, the potential to increase referrals to therapy and the increased revenue generated from those referrals might offset some costs.

In addition to cost issues, there are numerous treatment considerations with robotic therapy. For such interventions to be used in the clinic, the benefit must be established through ongoing clinical research trials. Currently, a motor learning approach is the generally accepted method to retraining movement with neurologically impaired individuals. Motor learning theory has been incorporated into therapy practice since the 1990s when Carr and Shepard advocated its use with NDT.[50] Regardless of the treatment philosophy, in general the adopted strategy is a principle of active, high repetition, task-specific practice.

Before bringing a robot into the clinic as a training tool, a clinician might ask if the robot can provide these needed practice conditions. Therapists will also want to know that adequate and/or varied learning conditions can be provided with a robotic device.

Another hurdle to overcome before robotics become a standardized treatment tool may be acceptance from the clinicians themselves. Therapists pride themselves on their ability to use their hands for evaluation and treatment. Their hands are the "tools of the trade." Clinicians may feel that the robot eliminates this aspect of practice that they feel is implicit to their profession. Other clinicians may fear that new technology could replace them in the clinic. Yet, the ability to assess and plan for the patient's individual needs is still dependent on the therapist's expertise and judgment. Robotics are technologies that are developed to assist therapists in attaining optimal outcomes for patients. In treatment, a robot may replace the therapist's hands to assist with heavy, challenging, or repetitious movement and ease physical strain on the therapist. A robot could also be used as a tool to allow for massed or varied practice of a difficult movement task. The therapist's hands and eyes will continue to provide the information that is used to evaluate the patient's movement strategies. Data from the robot can quantify what clinicians may be seeing and feeling (see the section, "Quantifying Impairment Using Robotic Devices") and can provide them with objective information on current performance that can be compared to past and future performance.

Future Directions

Whereas the last decade has taken rehabilitation robotics from concept to reality, the upcoming years will test these devices with extreme rigor to determine whether they should be considered as daily treatment options across various patient populations. Furthermore, advances in technology will result in these machines becoming lighter and more powerful, perhaps opening up new opportunities and therapies. Before devices like those profiled in this article can be made more effective, we must first understand which interventions best promote recovery. Once a particular mode of intervention has been shown to be effective, it only makes sense to then wonder whether a robotic device can help deliver it more effectively. The design and construction of devices that are not based on evidence-based practice or on solid therapeutic principles shown to be effective will surely lead to failure.

Robotic devices must also overcome the cost hurdles discussed in the section "Clinical Considerations When Incorporating Robotic Devices into Rehabilitation Centers." Krebs et al.[13] proposed that the MIT-MANUS could be used in a classroom fashion, where one therapist could oversee multiple patients who were each using the device. Such practice is currently being performed in Austria with the Lokomat, where one technician simultaneously trains more than one subject at a time on two devices side by side. Ultimately, the safety of these devices must be shown to be such that the occurrence of patient injuries is no higher than what is seen routinely in clinics.

We must also evaluate patient satisfaction and therapist satisfaction with the clinical use of rehabilitation robots. Krebs et al.[8] surveyed their research subjects; even though all subjects felt that the robot training was productive and assisted their recovery, they all preferred the therapist to the robot. Even though clinical rehabilitation robots mostly work in tandem with therapists rather than autonomously, issues such as patient comfort, anxiety, and tolerance must be taken into account.

Finally, we propose that clinical acceptance in this field will come only after well-controlled studies are performed demonstrating the effectiveness of robotic devices. For each device, these studies will need to identify which patients are appropriate and will likely demonstrate improvements in function, training parameters, training dosages, and other determinants surrounding the therapeutic intervention. To date, we have relied on heuristic rules for establishing parameters and dosing the therapies, because there were little or no foundations from which to work. Now that there is a growing body of literature in the field of rehabilitation robotics, our next steps must be to design, build, and test devices based on evidence and not assumption.

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Richard F. Macko, MD; Joseph Hidler, PhD

JRRD Guest Editorial

Exercise after stroke and spinal cord injury: Common biological mechanisms and physiological targets of training

INTRODUCTION

Over the past decade, various novel exercise therapies have emerged as a unifying approach to improving physiological fitness and physical function for individuals with neurological mobility impairments. Inspired initially by seminal studies in spinalized cats, models of locomotor relearning have advanced from bench to bedside in human spinal cord injury (SCI) and been applied to the study of exercise rehabilitation for individuals with hemiparetic stroke. Hence, a new and rapidly evolving science of clinical exercise physiology is now being established in neurological disability, with stroke and SCI constituting the leading edge in clinical and translational research. Out of this research, several common themes in conceptual training strategies and mechanisms of exercise-mediated adaptations are emerging that appear mutually informative to stroke and SCI investigators. This special issue of the *Journal of Rehabilitation Research and Development* is dedicated to veterans disabled by stroke and SCI and aims to advance our understanding of the biological mechanisms by which exercise may improve health and function following central nervous system (CNS) injury.

The general message is that exercise models can be targeted to affect multiple physiological systems that determine long-term health and functional outcomes in both stroke and SCI. Exercise therapy can be considered a multisystem model that includes the key domains of adaptations in CNS sensorimotor control; cardiovascular-metabolic health; and body composition, including bone health (**Figure**).

This issue highlights the multisystem model of exercise-mediated adaptations by examining selected, promising exercise intervention models for stroke and SCI, which are outlined in the remainder of this editorial.

EXERCISE-MEDIATED NEUROPLASTICITY IN STROKE AND SPINAL CORD INJURY

The model of task-oriented exercise training is based on advances in our understanding that task-repetitive training can potentially alter CNS plasticity at multiple levels, even years after a disabling neurological event. While brain plasticity and motor learning during upper-limb stroke rehabilitation have received the most study, convincing evidence now exists that lower-limb

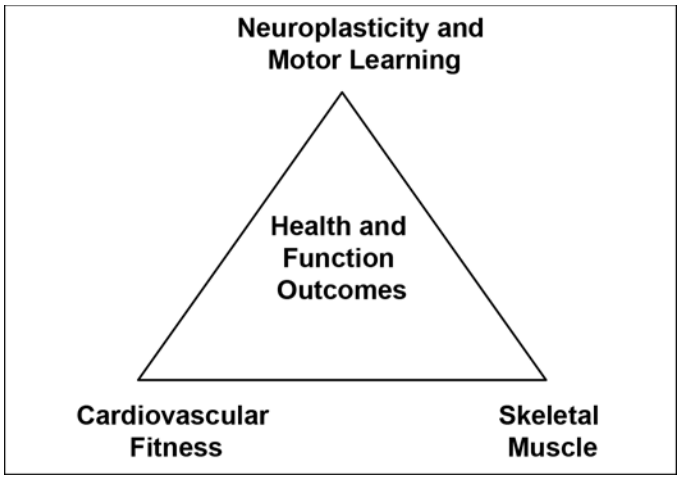

Figure.
Exercise therapy as multisystem model that encompasses adaptations in central nervous system sensorimotor control; cardiovascular-metabolic health; and body composition, including bone health.

motor control and locomotion are modifiable by exercise training. Forrester et al. (p. 205) review new evidence for neural plasticity, through which ankle and knee motor control are modifiable with task practice in patients with chronic hemiparetic stroke. Patterson et al. (p. 221) underscore the clinical relevance by providing the first report of the long-term effects (6 months) of progressive treadmill training on gait temporal-distance parameters in 39 patients with chronic stroke. Their data show that treadmill training improves selected gait temporal-distance parameters (but not symmetry) and ambulation across a number of different gait demand conditions, consistent with locomotor learning. Lynskey et al. (p. 229) provide a translational research overview of animal and human data on neuroplasticity after SCI, the potential for exercise-mediated neuroplasticity, and molecular mechanisms that may help bridge the gap between animal research and human intervention. Their promising conclusions are that activity-dependent plasticity is possible across multiple levels of the neuroaxis—spinal, cortical, and subcortical—and that multiple strategies, including electrophysiological stimulation and pharmacological and/or gene therapy can potentially enhance plasticity processes, defining directions for future mechanistic research.

CARDIOVASCULAR HEALTH BENEFITS OF EXERCISE

Based on animal studies in spinalized cats, variants of treadmill training have emerged as models for locomotor relearning in SCI and stroke rehabilitation. These training models are also targeted at improving other outcomes, including cardiometabolic health. Hicks and Martin Ginis (p. 241) provide a comprehensive overview of studies showing that exercise training improves lipid profiles, glucose tolerance, and psychological well-being. Similarly, Ivey et al. (p. 249) provide evidence that treadmill training in patients with chronic stroke improves not only ambulatory function but also fitness and cardiometabolic health even decades after stroke. Collectively, these findings support a rationale for regular exercise to reduce insulin resistance and improve cardiovascular health and fitness for individuals with SCI- and stroke-related disabilities.

STRUCTURAL-METABOLIC CHARACTERISTICS OF MUSCLE AND BONE HEALTH AFTER STROKE AND SPINAL CORD INJURY

After SCI, major structural and metabolic abnormalities exist in skeletal muscle, including gross muscular atrophy and a major shift to a fast, myosin heavy-chain muscle molecular phenotype that fosters insulin resistance. In patients with stroke, Hafer-Macko et al. (p. 261) report remarkably similar abnormalities in hemiparetic muscle linked to increased expression of tumor necrosis factor-α in the inflammatory pathway, a common denominator for atrophy and insulin resistance. McKenzie et al. (p. 273) report results of the first human genome survey in skeletal muscle of stroke patients that profiled families and included 116 genes that differ in expression between hemiparetic and nonparetic leg muscle. These findings suggest that a fundamental metabolic shift toward anaerobic metabolism in hemiparetic skeletal muscle is accompanied by abnormalities in gene expression for muscle contractile proteins, inflammatory mediators, cell cycling, and signal transduction.

Dudley-Javoroski and Shields (p. 283) provide an overview of the major skeletal muscle and bone abnormalities and their rapid time course after SCI. They report the promising finding that early functional electrical stimulation elicits appropriate mechanical load, preserving muscle mass and trabecular bone integrity, which is important for preventing fractures in this population. Unfortunately, bone health has received much less attention in the stroke population. Eng et al. (p. 297) clearly define stroke as a model of disuse osteoporosis with an alarmingly high fall rate and fracture risk. These investigators outline the evidence that structured exercise potentially improves indexes of balance, preserves femoral neck bone density, and improves trabecular bone content. In addition, this novel community-based exercise intervention holds promise for community translation.

INNOVATIVE EXERCISE MODELS

So that implementation of exercise programs that improve care for individuals with disabilities can be expanded, models must be customized across a broad range of deficit severities and be extended to the community. As Rimmer et al. (p. 315) outline, individuals with stroke have numerous environmental and personal barriers to exercise, including cost, access, and a lack of confidence that expertise or appropriate programs are available in their community. Macko et al. (p. 323) report a pilot study of adaptive physical activity conducted in Italy to improve basic mobility function for older individuals with chronic stroke. Stuart et al. (p. 329) propose exercise models designed for community translation that may have public policy implications as we consider how to better address the long-term health and wellness of individuals with chronic neurological disability.

ADVANCED TECHNOLOGIES FOR DELIVERING ACTIVITY-BASED EXERCISE

Throughout this issue, the underlying theme is that activity-based interventions have widespread health benefits ranging from changes in neural behavior to enhanced muscle and bone function. Unfortunately, delivering such interventions to individuals after stroke and SCI is difficult because of the severity of their motor impairments. Hidler et al. (p. 337) discuss the introduction of robotics into rehabilitation and how these devices can deliver mass-practice therapies. Preliminary evidence is also provided demonstrating the cardiovascular benefits of robotics-based gait training in individuals after SCI.

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Automating activity-based interventions: The role of robotics

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Abstract—We have seen a continued growth of robotic devices being tested in neurorehabilitation settings over the last decade, with the primary goal to improve upper- and lower-motor function in individuals following stroke, spinal cord injury, and other neurological conditions. Interestingly, few studies have investigated the use of these devices in improving the overall health and well-being of these individuals despite the capability of robotic devices to deliver intensive time-unlimited therapy. In this article, we discuss the use of robotic devices in delivering intense, activity-based therapies that may have significant exercise benefits. We also present preliminary data from studies that investigated the metabolic and cardiac responses during and after 6 months of lower-limb robotic training. Finally, we speculate on the future of robotics and how these devices will affect rehabilitation interventions.

Key words: activity-based rehabilitation, cardiovascular, gait, Lokomat, metabolic response, rehabilitation, robotics, spinal cord injury, treadmill training, walking therapy.

INTRODUCTION

In the articles of this special *Journal of Rehabilitation Research and Development* (*JRRD*) issue, we have presented numerous examples of how effective activity-based therapies can improve important health qualities in individuals following stroke and spinal cord injury (SCI). For example, following long-term manual-assisted treadmill training, individuals with incomplete SCI demonstrate lower total cholesterol and low-density lipoprotein, increased muscle mass, and a muscle fiber-type conversion to more fatigue-resistant type IIa and I fibers (see Hicks and Martin Ginis, p. 241, this issue). Similar improvements can be observed in stroke patients, where improvements in cardiovascular performance, muscle endurance, and functional gait can be realized with exercise-based interventions (Hafer-Macko et al., p. 261, this issue). What these and other studies have demonstrated is that with appropriate interventions, individuals with neurological injuries can realize important cardiovascular and metabolic benefits of exercise-based interventions beyond simply improvements in function.

While exercise is clearly important to the health and well-being of individuals after stroke, SCI, and frankly most neurological disorders, many of these individuals cannot participate in conventional exercise programs

Abbreviations: ASIA = American Spinal Injury Association, BWS = body weight support or body weight-supported, CVD = cardiovascular disorder, DC = direct current, DVT = deep venous thrombosis, FES = functional electrical stimulation, HR = heart rate, *JRRD* = *Journal of Rehabilitation Research and Development*, NRH = National Rehabilitation Hospital, RER = respiratory exchange ratio, SCI = spinal cord injury, V_E = ventilation, VO_2 = oxygen consumption.

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because of significant motor impairments. Therefore, while walking on a treadmill may benefit an individual's cardiovascular performance, the safety risks to someone with balance and stability deficits outweigh the potential benefits. One possible solution is to use interventions that are safer and reduce demands on coordination and balance. For example, functional electrical stimulation (FES) has been shown to be quite beneficial in building muscle mass and slowing the progression of bone mineral loss in SCI (Dudley-Javoroski, p. 283, this issue). Studies have reported similar effects that have used FES-based bicycling in SCI, perhaps most notably the reported gains in health and well-being that Christopher Reeve experienced [1]. The limitations with such interventions are that they may not always be possible (e.g., sensate subjects may not tolerate electrical stimulation) and they do not necessarily allow for the practice of functional, coordinated movements. While pedaling a bicycle could surely be seen as a precursor to gait [2], functional walking needs to occur at some point. If an intervention could be designed that promotes intensive exercise in the context of a functional task (e.g., gait), improvements in both function and overall health may be realized. To this end, robotic devices may be one possible solution.

The original focus of robotics-based interventions was to take advantage of the fact that the central nervous system is quite plastic (Lynskey et al., p. 229, this issue) so that with intensive, task-specific movements, individuals with stroke and SCI can regain function and perhaps some level of independence. Significant evidence suggests that robotic therapy improves upper- and lower-limb function after SCI [3–4] and stroke [5]. Ironically, little has been reported on the exercise benefits individuals may experience following robotic therapy, particularly in gait. In this article, we review robotic technology, outline the potential benefits of using these devices for exercise-based interventions, and present some early evidence that suggests robotic-based interventions can have positive exercise benefits in individuals with neurological injuries.

REHABILITATION ROBOTIC DEVICES

Rehabilitation robotic devices come in many forms, none of which resembles *The Terminator* in the famous Arnold Schwarzenegger movie. While most rehabilitation robots attempt to re-create therapeutic interventions that are often used in the clinic, such as reaching movements or grasping objects, some robots offer greater capacities that would be daunting for a physical therapist to deliver. One cannot doubt that robots targeting the upper limbs may provide exercise benefits if they allow subjects to practice repetitive reaching under some level of resistance. However, one could argue that other less-sophisticated interventions could provide the same benefits for a fraction of the cost. We therefore propose that the role of upper-limb robots will likely continue to focus on improving motor function rather than exercise benefits. While this role may be true for the upper limb, for which subjects can perform interventions in a seated and therefore safe position, providing gait-training interventions poses additional challenges.

As outlined in the articles by Macko et al. (p. 323) and Hicks and Martin Ginis (p. 241) in this *JRRD* issue, treadmill training following stroke and SCI has significant cardiovascular and muscular effects. Yet providing such an intervention to individuals with poor balance and stability provides added risks, particularly if the intensity of the intervention is near the individual's limits. Robotic gait trainers provide an excellent alternative because they add a component of safety for the patient and therapist that allows individuals to train at higher intensity levels for longer durations. While we highlight the Lokomat (Hocoma AG; Volketswil, Switzerland) robotic gait-orthosis in an article by Colombo et al. [6], we need to stress that many other gait-training systems are now being developed that parallel the Lokomat [7–10].

The Lokomat was developed in the late 90s to help automate manual-assisted body weight-supported (BWS) treadmill training. The device, as shown in **Figure 1**, is an exoskeleton that attaches to the outside of the subject's legs and assists the subject as he or she ambulates on the treadmill. Small direct current (DC) motors drive the hip and knee joints while dorsiflexion is provided at the ankle with two elastic straps. The latest version of the Lokomat control software allows for variable robot assistance, ranging from full passive mode in which the device moves the subject's legs through a prescribed trajectory to a compliant mode in which the robot provides no active assistance. Recently, a pediatric Lokomat version was released to the public that allows children approximately 4 to 12 years of age to participate in gait-training programs.

The major benefits of training with the Lokomat are that patients can practice intensive gait training early

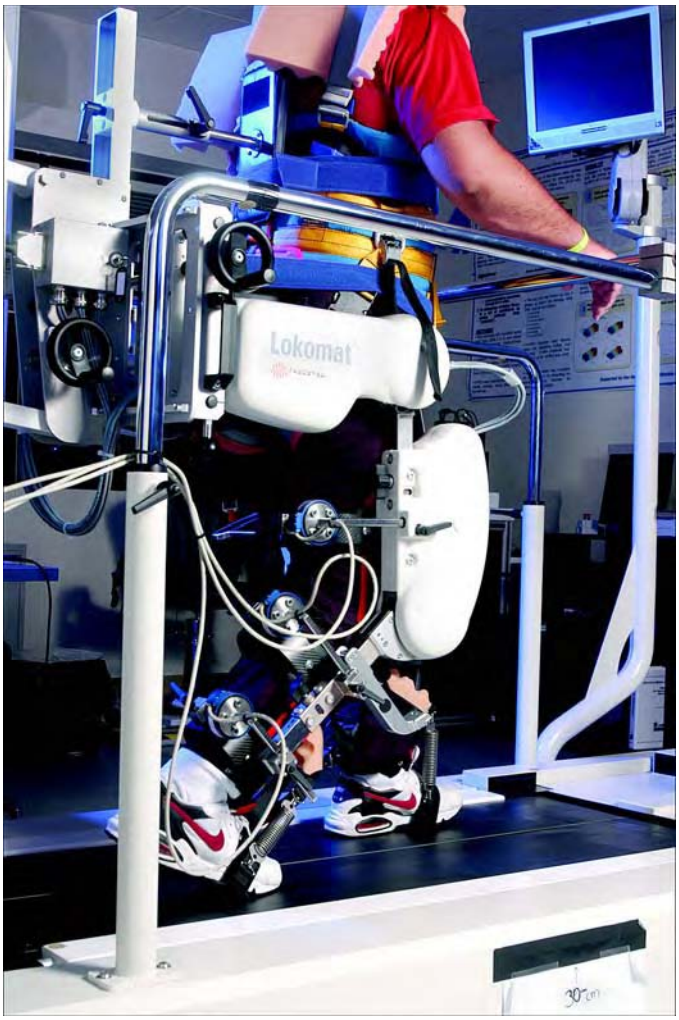

Figure 1.
Lokomat (Hocoma AG; Volketswil, Switzerland) robotic gait orthosis.

after their injuries in a safe and controlled environment. DeJong and colleagues recently published a longitudinal study that looked at factors important to stroke outcomes [11–12]. They found that early interventions (e.g., time postinjury) and intensity were factors that strongly correlated with gains in function. These two factors, early training and intensity, are supported by the Lokomat. First, because of the BWS system, subjects can practice walking much earlier in their rehabilitation program, since the risk of falling is eliminated. This added security allows individuals to begin walking as soon as they are medically stable, which is important not only for functional returns but also for prevention of secondary complications such as deep venous thrombosis (DVT), muscle atrophy, cardiovascular deterioration, and pneumonia. One could also argue that getting subjects to walk early after their injuries can have positive psychological effects. Second, the intensity of the training can be graded by adjusting of the BWS level, changing the walking speed, and varying the amount of robot assistance. Each of these training parameters place additional cardiovascular demands on the individual and can be altered both within and across training sessions. In addition, unlike treadmill training sessions that may be limited by therapist fatigue, training sessions on robotic devices like the Lokomat are time-unlimited, since they are actuated by DC motors.

Most of the studies to date have focused on the lower-limb robotic devices as clinical training tools that improve walking ability, yet they have overlooked the added exercise benefits of the intervention. The U.S. Surgeon General recommends that “persons of all ages should include physical activity in a comprehensive program of health promotion and disease prevention and should increase their habitual physical activity to a level appropriate to their capacities, needs, and interest,” and this is echoed by the National Cholesterol Education Panel, American Heart Association, Centers for Disease Control and Prevention, American Diabetes Association, American College of Sports Medicine, and others. Unfortunately, the reality is that diminished levels of fitness account for a large part of accelerated cardiovascular disorder (CVD) and increased body fat after SCI [13–20] and 25 percent of young, healthy persons with SCI have a level of fitness insufficient to perform essential activities of daily living [21]. We know that fitness and well-being are improved in persons with SCI by exercise conditioning [13,22–27] and higher levels of fitness are associated with reduced CVD risk [28–34]. Furthermore, several reports have highlighted the beneficial effect of exercise conditioning in persons with risk factors for CVD [28–29,32–34]. Here, we highlight three studies that have investigated metabolic and cardiac responses in SCI during robotic-assisted gait training, as well as some preliminary work investigating changes in cardiovascular performance after long-term robotic gait training.

METABOLIC AND CARDIAC RESPONSES DURING ROBOTIC GAIT TRAINING IN SCI

Israel et al. published a recent study that compared muscle activation patterns and metabolic responses in

individuals with incomplete SCI who walked on a treadmill with either therapist assistance or Lokomat assistance [35]. Twelve individuals classified as C or D on the American Spinal Injury Association (ASIA) Impairment Scale [ASIA, 2004] were tested on two separate sessions. In one session, two therapists assisted the subject as he or she ambulated on a treadmill under 30 to 40 percent BWS. Each therapist provided enough assistance so that the subject could clear his or her toe during swing and achieve adequate knee extension during stance. In a separate test session, each subject walked under the same levels of BWS, but the Lokomat assisted rather than the therapists. One should note that in these tests, the Lokomat was run in passive mode. In this mode, the Lokomat moves each subject's legs through a prescribed trajectory regardless of the subject's intensions (akin to a continuous passive machine). Each subject was asked to walk "with the robot" and try to match the machine's movements to the best of his or her ability. For both treadmill (therapist-assisted) and Lokomat sessions, muscle activity was collected from tibialis anterior, soleus, medial gastrocnemius, vastus lateralis, rectus femoris, and medial hamstrings. Metabolic measurements included rates of oxygen consumption (VO_2) and carbon dioxide production, while metabolic cost (or equivalent power) was calculated from these metrics.

The investigators found that during therapist-assisted treadmill walking, individuals with incomplete SCI demonstrated significantly greater VO_2 and metabolic cost than during Lokomat-assisted training. On average, subjects achieved VO_2 levels of 14.0 ± 3.9 mL/kg/min when walking on the treadmill with the therapist's assistance, but only 9.0 ± 2.4 mL/kg/min when walking with Lokomat assistance. For power measures, subjects generated approximately 3.1 ± 1.4 W/kg when walking with therapist assistance but only 1.9 ± 0.8 W/kg with Lokomat assistance. (Measurements are mean ± standard deviation unless stated otherwise.) While significant differences were observed in metabolic parameters for treadmill and Lokomat walking, in general, no significant differences were found in muscle activation patterns in six lower-limb muscles (for amplitude or timing of activity) during the gait cycle.

We should reiterate that metabolic differences were observed between therapist-assisted and Lokomat-assisted walking trials when subjects were instructed to walk as the device walked and match the kinematic trajectory prescribed by the Lokomat. However, in separate trials in which subjects were asked to maximize their effort during therapist- and Lokomat-assisted trials, no differences were found in metabolic parameters or muscle activation patterns.

The results from Israel et al.'s study indicate that similar muscle activation patterns and metabolic responses can be achieved in the Lokomat when compared with therapist-assisted training [35]. However, this finding only applies when the appropriate instructions or training conditions are given to the subject. This finding exposes a serious limitation with robotics. That is, if too much BWS or robotic assistance is provided to the subject or if the instructions are not clear, the subject may become complacent and allow the robot to assume a greater workload. As a result, the cardiovascular demands on the subject will decrease dramatically. In therapist-assisted treadmill training, this decreased effort level is not an issue, since therapists can continuously sense how much effort they are providing the subject and therefore indirectly measure the subject's effort level. This finding clearly emphasizes that therapists need to know the robot equipment, understand how to change parameters to continuously challenge the subjects, and be able to assess when the workload is inappropriate for the subject's abilities.

Nash and colleagues investigated metabolic and cardiac responses during Lokomat training in a 25-year-old female subject with a motor complete C3 to C4 (third to fourth cervical vertebrae) chronic SCI [36]. In this study, they measured VO_2, minute ventilation (V_E), and heart rate (HR) during seated resting and supported standing and while walking 40 minutes in the Lokomat. They found that the resting VO_2 of 50 mL/min increased immediately at the onset of walking to 118 mL/min, while V_E increased from 7.2 L/min in rest to 9.6 L/min during walking. HR also increased from 76 bpm during rest to 93 bpm during Lokomat walking.

The findings in this study indicate that even in motor complete SCI with lesions interrupting vagus and phrenic nerve pathways, significant cardiac responses can be elicited. While the investigators speculated that the increased metabolic response was attributed to reflex activity generated by stretching the muscles, this claim cannot be validated, since muscle activity was not recorded in this experiment. What this study does highlight is strength of robotic gait trainers. Since the robot can stabilize the lower limbs during training, individuals with no function below their injury level can be trained for extended durations. Although therapists could administer similar interventions,

whether they could maintain consistency over an extended training session is questionable. Additionally, therapists engaged in treadmill training paradigms have reported repetitive strain injuries and lower back problems. Training individuals with motor complete SCI may have additional health benefits beyond cardiovascular conditioning, such as prevention of DVT, improved circulation, slowing of bone mineral loss, and improved psychological state. Unfortunately, no studies to date have reported such effects, so these potential benefits are speculative at this point.

CHANGES IN METABOLIC AND CARDIAC RESPONSES FOLLOWING LONG-TERM ROBOTIC-ASSISTED GAIT TRAINING IN SCI

While the studies just described investigated within-session changes in metabolic and cardiac responses during robotic-assisted walking, they did not investigate whether people with SCI will experience a cardiovascular or metabolic training effect following repeated training sessions. A randomized controlled trial is currently underway at the National Rehabilitation Hospital (NRH) in Washington, DC, and the Miller School of Medicine, University of Miami, to quantify the effects of 6 months of robot-assisted BWS treadmill training on selected measures of fitness in persons with SCI. Subjects are people with ASIA C or D traumatically induced SCI between 1 and 6 months postinjury.

Subjects are randomized to either exercise training using robot-assisted BWS treadmill training or usual rehabilitative care. The experimental group participates in 72 Lokomat training sessions lasting 1 hour, three times a week for 6 months. Here, subjects walk in the Lokomat at an initial training speed of 1.9 km/h, progressing to a maximum of 3.2 km/h. During the training sessions, the levels of BWS and robot assistance are decreased as tolerated at each training session so that weight-bearing and workload can be increased. Subjects walking in the Lokomat are encouraged by the physical therapist and a computer-based biofeedback system to actively move the robotic legs. Subjects in the experimental group often begin Lokomat training while they are inpatients, where the Lokomat training supplements the standard physical therapy they receive at NRH or The University of Miami. Since these subjects often continue outpatient therapy following their discharge, the Lokomat training simply supplements their usual care until they complete their outpatient therapy program. At that time, subjects only receive Lokomat training. The control group receives the same inpatient and outpatient therapy programs; however, they do not receive the supplemental Lokomat therapy.

Changes in metabolic responses are assessed for both groups at baseline and again at 3 and 6 months (**Figure 2**). A resting 12-lead electrocardiogram is performed and analyzed for rate, rhythm, and contraindications to exercise testing throughout the evaluation session [37]. Metabolic responses to exercise are continuously monitored by the open-circuit method on a metabolic analyzer as described by Nash et al. [36]. Resting metabolism and HR are measured for 6 minutes with the subject in the seated position, for controlling metabolic and chronotropic responses to the upright position, and after 6 minutes of BWS standing. The subject then ambulates in the Lokomat at the matched subpeak work rate of 1.8 km/h with the least BWS

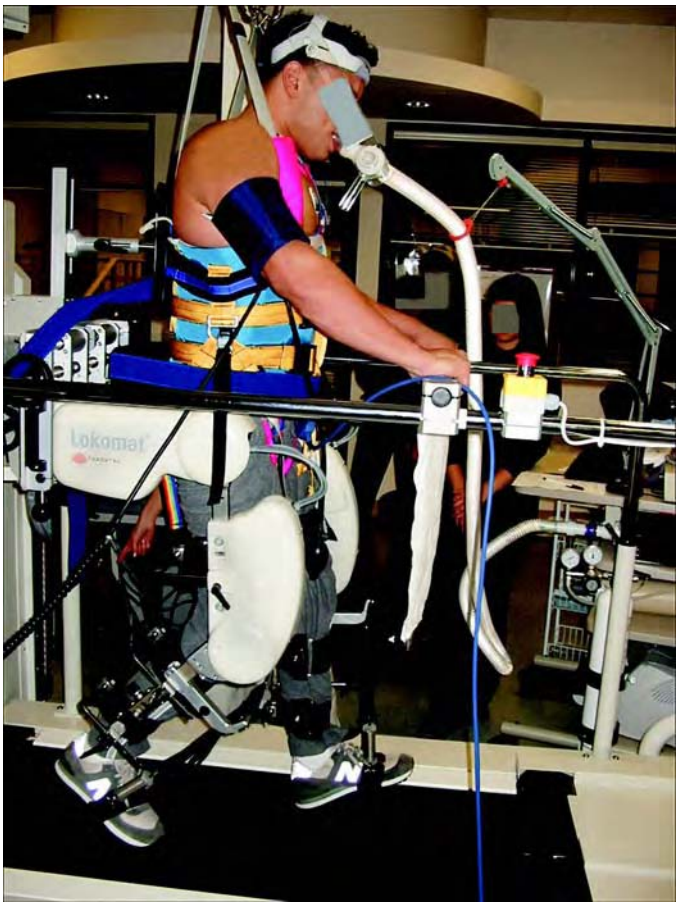

Figure 2.
Metabolic testing in Lokomat (Hocoma AG; Volketswil, Switzerland).

tolerated for 6 minutes. Both the 3- and 6-month follow-up metabolic tests are repeated at the same speed (1.8 km/h) and same percent BWS provided during the initial testing.

To date, five subjects have been trained on the Lokomat and four subjects have been assigned to the control group. The age range for the sample is 24 to 59 years, with an average age of 44.1 years. The **Table** summarizes interim trends for the subjects trained on the Lokomat.

The working hypothesis is that with the use of a standardized work rate on the Lokomat for all three tests, an exercise training effect in the intervention group would be reflected by lower resting and peak HRs, VO_2, and respiratory exchange ratio (RER) values on the 6-month test compared with the baseline test. Data from the 6-month test demonstrated a dramatic decrease in resting and peak HRs but a modest increase in VO_2 accompanied by a small decrease in RER at peak exercise. By comparison, mean values in the usual group for resting HR and peak HR decreased only 8.4 and 1.4 percent, respectively, while peak VO_2 increased 5.1 percent on the final test. While no statistical conclusions can be made from this small set of data, the trend indicates that a training effect may have been achieved after 72 sessions of Lokomat walking.

CONCLUSIONS AND FUTURE DIRECTIONS

While the future of robotics in neurorehabilitation programs is still unclear, early evidence suggests that interventions such as robotic-assisted gait training may improve gait as well as cardiovascular and metabolic performance. Some of the advantages of robotics devices in delivering intensive therapy have been outlined, such as the capability to train for longer time periods, at higher intensities, and in a well-controlled environment. However, using robotic devices has some disadvantages. These devices are very expensive, they sometimes break down and require routine service, and perhaps the biggest disadvantage, they do not have the same "feel" as therapists do. That is, for interventions such as therapist-assisted treadmill training, the therapist can continuously monitor important characteristics of the training, such as the subject's effort level, spastic contractions, and fatigue. While robots have high-resolution sensors that can also monitor such events, they currently are not programmed to do so. We hope that next-generation robots will have better monitoring capabilities and interact much more, providing "as needed" assistance. Integrating advanced concepts such as virtual reality [38] and quantifying impairments such as weakness and spasticity [39] has already begun. Adding measures of cardiac and metabolic responses would surely make these devices well-rounded additions to rehabilitation clinics.

Table.
Comparison of baseline and 6-month exercise test data following Lokomat (Hocoma AG; Volketswil, Switzerland) training.*

Variable	Baseline	6 Months	% Change
Resting HR (bpm)	103.0	67.2	–35.8
Peak HR (bpm)	131.8	84.4	–36.0
Peak VO_2 (mL/kg/min)	7.8	8.2	+7.0
V_E (L/min)	16.5	16.9	+2.4
RER	0.96	0.94	–2.1

*All values are group means.
HR = heart rate, V_E = ventilation, VO_2 = oxygen consumption, RER = respiratory exchange ratio.

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The authors have declared that no competing interests exist.

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Strength and Coordination in the Paretic Leg of Individuals Following Acute Stroke

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***Abstract*—The goal of this study was to determine whether acute stroke survivors demonstrate abnormal synergy patterns in their affected lower extremity. During maximum isometric contractions with subjects in a standing position, joint torques generated simultaneously at the knee and hip were measured, along with associated muscle activation patterns in eight lower limb muscles. Ten acute stroke survivors and nine age-match controls participated in the study. For all joints tested, stroke subjects demonstrated significantly less maximum isometric torque than age-matched control subjects. However, the synergistic torques generated in directions different than the direction that was being maximized were not significantly different between the two groups. According to electromyography (EMG) data, it was found that stroke subjects activated antagonistic muscle groups significantly higher than the control group subjects, suggesting that deficits in joint torque may be at least partially attributable to co-contraction of antagonistic muscles. Our findings suggest that a primary contributor to lower limb motor impairment in acute hemiparetic stroke is poor volitional torque generating capacity, which is at least partially attributable to co-contraction of antagonistic muscles. Furthermore, while we did not observe abnormal torque synergy patterns commonly found in the upper limbs, muscle activation patterns differed between groups for many of the directions tested indicating changes in the motor control strategies of acute stroke survivors.**

***Index Terms*—Hemiparesis, muscle, spasticity, stroke, synergies.**

I. Introduction

THERE are a number of mechanisms which may be responsible for gait abnormalities in individuals following stroke, including weakness [1], [7], [8], [32], [34], [35], [37], spasticity [5], [6], [15], [28], [26], [33], abnormal muscle activations [11], [14], [21], [24], [25], [29], and changes in joint mechanical properties such as passive tone [21], [30], [31]. Unfortunately, there is little consensus on how each of these behaviors contributes to abnormal motor function and consequently walking deficits following stroke (for a detailed review, see [8]).

In the upper limb of chronic stroke survivors, there is a strong presence of abnormal synergistic torque patterns that significantly reduce limb coordination and control during both static [2], [18] and dynamic [3], [4], [36] tasks. In the context of this work, synergy patterns are defined as the set of joint moments generated throughout the limb of interest for a given task. For example, Reinkensmeyer *et al.* [36] showed that when chronic stroke patients performed reaching movements along a linear rail, they often exerted significant forces perpendicular to the intended direction of movement which were consistent with the upper limb synergy patterns described by Brunnstrom [12]. Beer *et al.* [4] demonstrated similar patterns under dynamic conditions where stroke subjects exhibited strong elbow flexion and shoulder external rotation torques when abducting the arm and strong elbow extension and shoulder internal rotation torques when adducting the arm. These studies demonstrate that deficits in motor control are at least partially attributed to abnormal synergy patterns or equivalently, an inability to generated muscle forces and subsequently joint torques appropriate for a given task.

Multidimensional abnormal synergy patterns in the lower extremities were first quantified by [38] for individuals with cerebral palsy (CP). In this study, subjects were asked to execute maximum hip and knee flexion and extension exertions, during which secondary torques generated at adjacent joints were simultaneously quantified. It was found that individuals with CP demonstrated significant knee extension moments while maximizing hip extension and generated significant hip extension during knee extension exertions. Both of these strategies were different than age-matched controls and were consistent with the classically defined extension synergy commonly associated with individuals with CP.

In our previous work [34], we quantified lower limb isometric strength (e.g., peak volitional joint torques at the ankle, knee, and hip), torque synergy patterns, and muscle activation patterns in individuals with chronic stroke in a standing posture. This allowed us to assess important motor behaviors in a functional position, including vestibular inputs and the necessity to stabilize the trunk in order to maintain an upright position. In our experimental setup, we were able to quantify synergy patterns by investigating the joint torques generated in adjacent joints or axes while attempting to maximize the isometric joint torque along a different joint or axis. We found that the synergistic torque patterns used by both control subjects and stroke subjects were similar during ankle, knee, and hip exertions, however lower limb strength was significantly less in stroke subjects in six of eight exertion directions tested. We also found that stroke subjects tended to co-activate antagonistic muscles, which was at least one of the mechanisms causing deficits in strength.

While our previous work demonstrates that in the chronic stages of stroke, subjects do not exhibit abnormal synergy patterns in their lower extremities but do co-activate antagonistic muscles and have excessive deficits in strength, it is still un-

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TABLE I
CHARACTERISTICS OF STROKE AND CONTROL SUBJECTS

Subject	Gender	Age (years)	Injury	Days post-injury*	Fugl-Meyer
1	F	81	RCVA	19	18
2	M	71	LCVA	28	29
3	M	63	LCVA	43	21
4	M	56	RCVA	30	16
5	M	66	RCVA	27	22
6	M	64	LCVA	26	17
7	M	63	LCVA	23	24
8	F	60	LCVA	39	11
9	F	55	RCVA	36	13
10	M	62	LCVA	18	20

* Number of days between stroke and test date
LCVA/RCVA: Left/Right Cerebral Vascular Accident

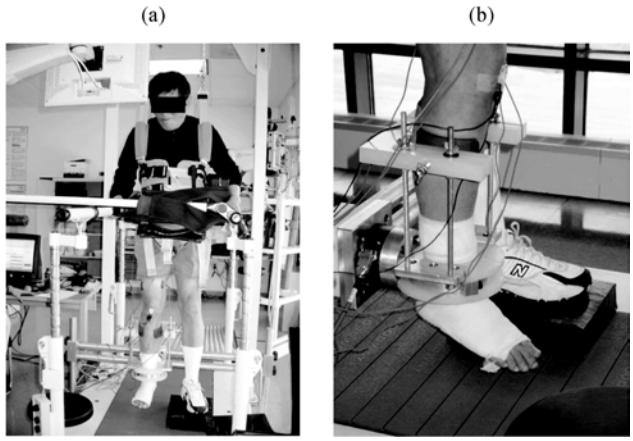

Fig. 1. Experimental setup for testing isometric torque at the knee and hip joints. A cast was placed around the subject's lower leg, and then clamped into a custom fixture extending from the load cell. The subject's trunk was supported with large bumpers around the pelvis.

known how these impairments develop throughout the stages of stroke recovery. By testing acute stroke survivors, motor deficits can be quantified at the early stages of their injury, and then subsequent tracking of the development of these impairments can be observed over time.

In this study, our goal was to quantify peak volitional isometric knee and hip torques and multiaxial synergy patterns acute stroke subjects generate in their affected lower extremity. Additionally, by examining the muscle activation patterns exhibited during these exertions, we are able to better understand the potential causes of weakness and deficits in coordination, which may advance our understanding of lower limb motor impairments in individuals with acute stroke.

II. METHODS

A. Subjects

We tested ten acute hemiparetic stroke survivors (seven male, three female) and nine age-matched control subjects (five male, four female; mean age: 58.4 years), with details of both groups listed in Table I. Stroke inclusion criteria included unilateral lesion of the cortex or subcortical white matter with an onset less than six weeks prior to testing. Subjects were excluded from the study if they presented with severe osteoporosis, contracture limiting range of motion, cardiac arrhythmia, or significant cognitive or communication impairment which could impede the understanding of the purpose of procedures of the study. All experimental procedures were approved by the Institutional Review Board of Medstar Research. Informed consent was obtained prior to each test session.

Motor function was evaluated in the paretic lower extremity using the Fugl-Meyer (FM) scale [23], which ranges from 0 to 34 with the maximum score indicating no observable deficits in function. In order to study hemiparetic stroke patients with mild to moderate impairment levels, we targeted subjects having a FM score in the range of 10–30.

B. Experimental Apparatus

The novel test apparatus used in this study was custom built, allowing for the simultaneous measurement of strength and coordination in the leg with subjects in the standing position. The device, as illustrated in Fig. 1, consists of a 6-degrees-of-freedom (DOF) load sensor (JR3 Inc., Woodland, CA) mounted to a custom frame, which has 4-DOF of adjustability. The subject's leg was rigidly connected to the load cell by casting the lower leg with Delta-Lite fiberglass casting (Johnson & Johnson, Piscataway, NJ) and then placing an aluminum clamp around the cast which in turn was mounted to the load cell. A vertical shank support extending from the aluminum ring was used to minimize varus–valgus movements at the knee [Fig. 1(b)]. Because testing was done with the subject in the standing position, the subject was placed in a harness and attached to a body-weight support system (Woodway USA, Waukesha, WI) in order to eliminate the risks for falls. No support was provided by the system during each trial, however between trials, subjects often sat in the harness like a swing in order to minimize fatigue in their legs. Additionally, the trunk was stabilized in the anterior–posterior and medial–lateral planes using large bumpers that pressed on the abdomen, lower back, and on each side of the pelvis [Fig. 1(a)]. The bumpers were compressed so that during the experiment, the geometry of the subject's leg did not change during the exertion portion of the trial. The subject's leg was positioned so that the knee and hip joints were flexed approximately 40° and 30°, respectively.

Surface electromyography (EMG) were recorded differentially from the gastrocnemius, medial hamstrings, rectus femoris, gluteus medius, gluteus maximus, adductor longus, vastus medialis, and vastus lateralis muscles using a Bagnoli-8 EMG system (Delsys, Inc., Boston, MA). Forces and torques from the load cell, and all EMG data were anti-alias filtered at 500 Hz prior to sampling at 1000 Hz using a 16-bit data acquisition board (Measurement Computing, PCI-DAS 6402, Middleboro, MA) and custom data acquisition software written in Matlab (Mathworks Inc., Natick, MA).

C. Protocol

The maximum isometric torque at the hip and knee joints of each subject was measured in eight different directions, namely hip flexion–extension, hip abduction–adduction, hip internal–external rotation, and knee flexion–extension. Before collecting any data, each subject was allowed to practice generating maximum isometric contractions along the preferred direction a minimum of three times. Following a rest period, the subject was then asked to produce their maximum torque for the joint being tested. During practice and each experimental trial, a visual display that looked like a speedometer was shown to the subject. Subjects were instructed to rotate the speedometer as far as possible, thereby observing the generation of their maximum torque. The movement of the speedometer was only sensitive to the torque being generated along the preferred direction in order to emphasize the direction of torque exertion. Each torque exertion lasted approximately 4–5 s, followed by a 1-min rest period. Verbal reinforcement was provided throughout the experiment to encourage the subject to exert their maximal effort.

A total of three trials were run for each of the primary directions, totaling 24 trials. Eight test epochs, with each epoch consisting of three trials for each direction, were applied sequentially. The order in which the primary direction was selected was randomized, with 1-min breaks in between trials. This procedure was implemented to minimize bias associated with the order in which torque direction was tested. The paretic leg was tested in all of the stroke subjects, while we randomized which leg was tested (e.g., dominant/nondominant) in the age-matched control group. It should be noted that we were unable to test the unimpaired stroke leg since this would have required stroke subjects to stabilize themselves for the duration of the study on their affected leg, which was not possible.

D. Data Analysis

The forces and torques measured at the load cell were transformed back to the subject's knee and hip joints in order to provide real-time visual feedback to the subject during each trial and for post experimental analysis. With the load cell positioned behind the subject just above the ankle, forces and torques generated at the knee and hip joints were calculated using the technique described in the [16].

For each of the eight torque directions tested, the maximum volitional primary torque ($\mathrm{Tp}_{\max}$) generated along the intended direction was identified as the peak torque sustained for 200 ms observed across the three trials (Fig. 2). This smoothing technique helped to eliminate spikes in torque if the subject jerked their limb during a specific exertion. The magnitude of the corresponding secondary torques Ts exerted along the other directions produced at the time of occurrence of $\mathrm{Tp}_{\max}$ was also identified. For example, during maximum hip flexion exertions, secondary torques consisted of those generated along the knee flexion-extension axis, hip abduction–adduction axis, and hip internal–external rotation. Secondary torques generated during all trials were normalized to the maximum primary torque measured for that particular joint axis and direction such that secondary torques were expressed as a percentage of volitional max. In cases where secondary torques exceeded 100%, this indicated that the subject generated less torque while attempting to maximize that particular direction than when they were trying to maximize a different direction.

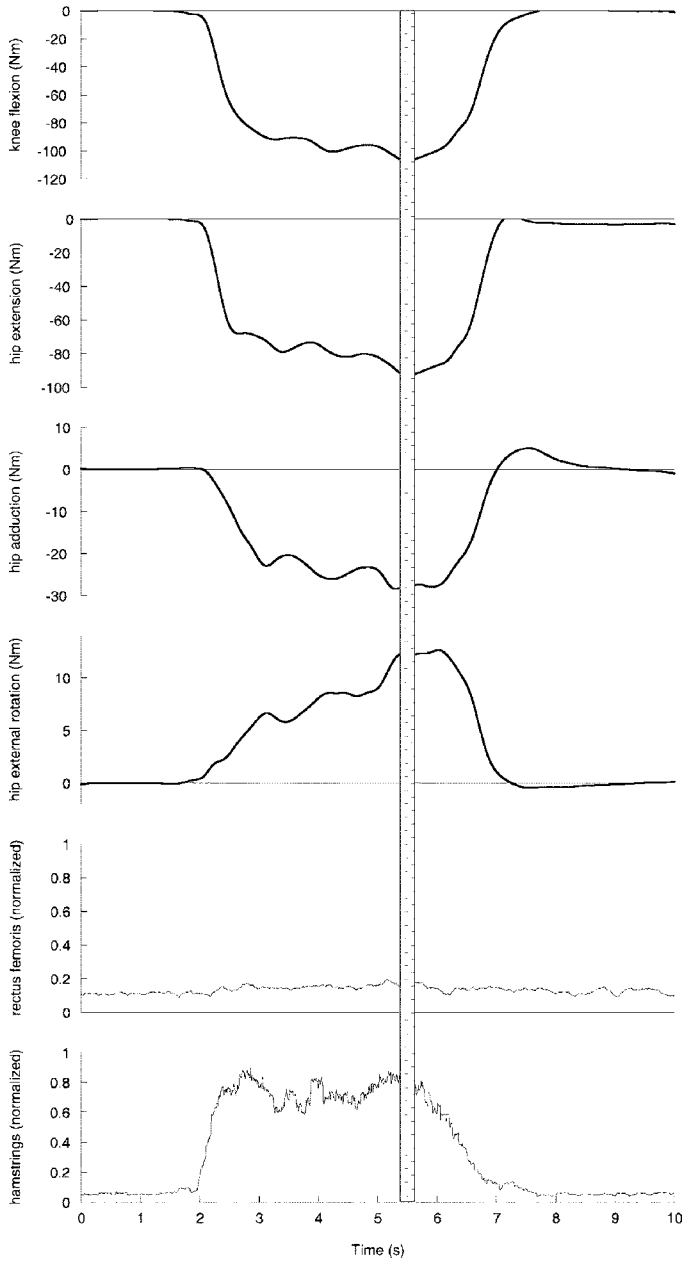

Fig. 2. Example tracing of joint moments generated simulataneously at the hip and knee joints during a knee flexion task, along with two corresponding EMG traces (rectus femoris and hamstrings). The shaded region indicates a 200-ms time window which was used to identify maximum exertions along the primary torque direction. Secondary torques and muscle activation levels generated at the time of the max could then be identified.

EMG activity from each muscle was band-pass filtered (20–450 Hz), full-wave rectified, and then smoothed using a 200-point root mean square (rms) algorithm. EMG activity for each trial was normalized to the maximum EMG value observed across all trials for each respective muscle. This allowed for muscle activations demonstrated during maximum exertions to be expressed as the percentage of peak activity observed in

each muscle. The magnitude of EMG activity for each muscle was identified at the time the primary torque $(\mathrm{Tp}_{\max})$ was generated.

E. Muscle Cocontraction Index

It has been previously reported that weakness following stroke may result from subjects simultaneously activating their antogonist muscles, which would negate a portion of the power generated by the agonist muscle groups [13], [24]. In order to determine whether any observed weakness could be attributed to the co-activation of antagonistic muscles, we computed a co-contraction index (CI) for each primary torque direction as follows:

$$\mathrm{CI} = \frac{\sum \mathrm{PCSA}_i * \mathrm{EMG}_{\mathrm{agonist},i}}{\sum \mathrm{PCSA}_j * \mathrm{EMG}_{\mathrm{antagonist},j}} \tag{1}$$

where PCSA is the physiological cross sectional area of the muscle [10], i and j are the indices of each respective agonist and antogonist for each joint tested. Here, the co-contraction index is the total activity demonstrated in the agonist muscle groups divided by the total muscle activity demonstrated in the antagonistic muscle groups for each primary torque direction. Scaling the muscle activity by the PCSA is important since activity in large muscle groups will generate significantly higher forces than activity in muscles with smaller cross-sectional area. In essence, the CI indicates how much co-activation of antagonistic muscle groups subjects exhibit, where a higher CI is indicative of higher agonist muscle activity (versus antagonist); while a low CI is indicative of abnormally elevated antagonist activity. The latter would result in decreasing levels of torque exerted at the joint since the antagonist muscle groups would counteract some of the power generated by the agonist muscle groups.

F. Statistical Analysis

The maximum primary torque exerted by the stroke and control subjects in each of the eight directions was compared using a single-factor ANOVA. Differences in the amplitude of muscle activations exhibited during each maximum exertion direction were examined by comparing the normalized EMG for each muscle between groups using a Student *t*-test.

We also investigated how stroke subjects generate synergistic joint torques adjacent to the primary joint axis, which is an indirect measure of coordination. Using the normalized torque each subject generated as secondary torques during each of the eight primary torque directions, a single-factor ANOVA was used to compare torque synergies between the stroke and control groups. All statistical tests were done with $\alpha = 0.05$.

III. RESULTS

A. Primary Torque

During isometric maximum exertions at the hip and knee joints, acute hemiparetic stroke subjects exerted significantly less torque than age-matched control subjects in all directions tested $(p < 0.05)$. Fig. 3 illustrates the mean maximum isometric joint torques for each direction tested along with the 95% confidence interval. It can be seen that deficits in strength in the stroke subjects range from 11% of control subjects to 48.8%. The mean joint torques are listed in Table II, expressed in absolute terms and as a percentage of torque generated by age-matched control subjects. It should be noted that the percentage of female controls subjects in the control group (44%) was slightly higher than in the stroke group (30%) which may underestimate the true strength deficits in the acute stroke group.

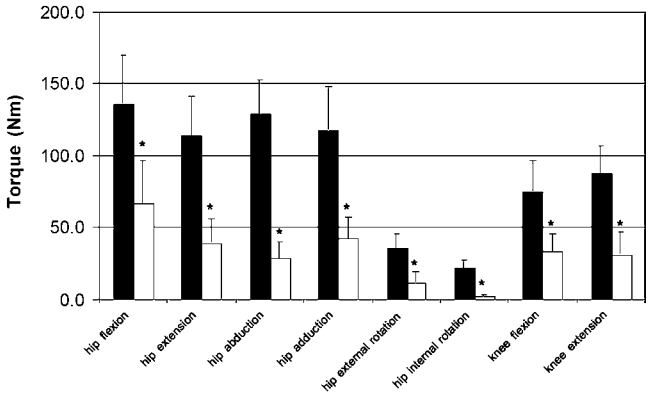

Fig. 3. Maximum primary isometric torques for the control and stroke subjects (black = control; white = stroke). (∗ indicates $p < 0.05$).

TABLE II
MAXIMUM ISOMETRIC JOINT TORQUE IN EACH GROUP†

Primary Torque Direction	Controls	Stroke	Percent of Control*
Hip flexion	136.3 (34.0)	66.6 (29.4)	48.8‡
Hip extension	113.9 (27.2)	39.7 (16.8)	34.9‡
Hip abduction	128.6 (23.7)	28.6 (11.4)	22.3‡
Hip adduction	117.9 (29.7)	42.5 (14.8)	36.0‡
Hip external rotation	36.0 (10.0)	12.2 (6.7)	33.8‡
Hip internal rotation	21.6 (20.9)	2.4 (1.3)	11.0‡
Knee flexion	75.2 (20.9)	33.4 (12.7)	44.5‡
Knee extension	87.6 (18.6)	31.4 (15.4)	35.9‡

† Torques listed are averages for each group, in Nm, along with 95% confidence interval in parentheses.
* Percent of control refers to the amount of torque stroke subjects generated normalized by the control torque values (e.g. $\mathrm{Torque}_{\mathrm{stroke}}/\mathrm{Torque}_{\mathrm{control}} \times 100$).
‡ Indicates statistically different ($p < 0.05$)

B. Secondary Torques and EMGs

As described in Section II-D, during maximum primary exertions at the hip and knee joints, the corresponding torques exerted at adjacent joints and/or axes were quantified. These secondary torques demonstrate the synergy patterns subjects utilize throughout the lower limb in order to maximize the joint torque along the primary direction. Results are reported during primary exertions along the hip flexion–extension, hip abduction–adduction, and knee flexion–extension axes. No differences were found in the synergy patterns expressed by the stroke subjects when compared to the control subjects during maximal hip internal or hip external rotation.

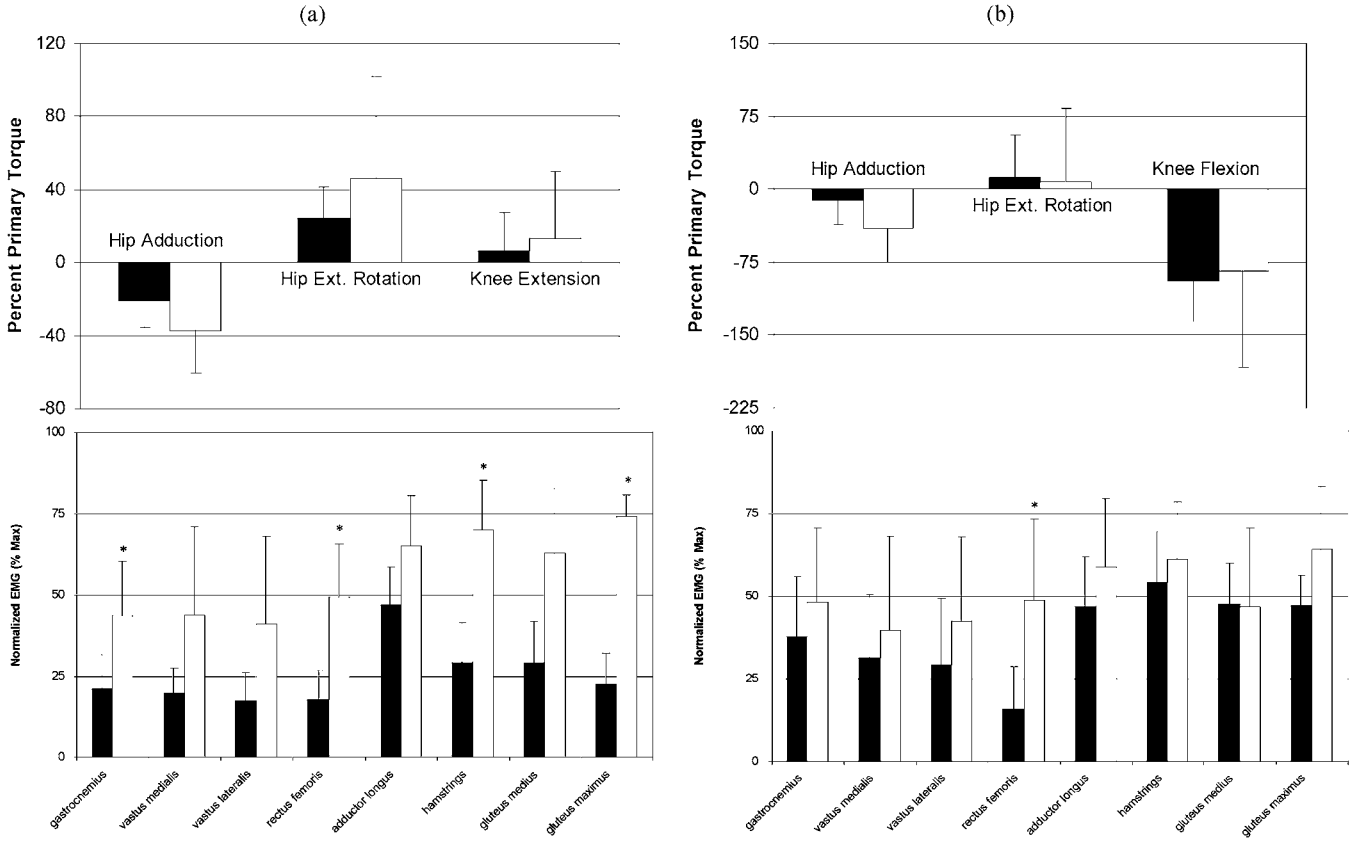

Fig. 4. Secondary torques generated during hip flexion (column a) and hip extension (column b) along with normalized muscle activity. No significant differences were found in secondary torques for either direction while differences in muscle activation levels were more prominent during hip flexion than hip extension between groups. Error bars indicated 95% confidence interval. (black = control; white = stroke) ($*$ indicates $p < 0.05$).

While generating maximum voluntary hip flexion torque, both control and stroke subjects also generated hip adduction and hip external rotation. As shown in Fig. 4(a), there was substantial variability in the amount of secondary torques produced during maximum hip flexion, however there were no significant differences in secondary torques between subject groups. Interestingly, when maximizing hip flexion torque, there were trends for muscle activity to be higher in the stroke subjects in most of the lower limb muscles, with significant differences occurring in the gastrocnemius, rectus femoris, hamstrings, and gluteus maximus ($p < 0.05$).

During maximal hip extension exertions, both groups exhibited hip adduction and knee flexion secondary torques [Fig. 4(b)]. There were no significant differences in secondary torques between the two groups. Similar to hip flexion exertions, there were trends for higher muscle activations in numerous muscles spanning both the hip and knee joints, although only rectus femoris was found to be significantly different between the two groups.

While attempting to maximize hip abduction torque, control subjects tended to generate simultaneous secondary torques along the hip flexion, hip internal rotation, and knee flexion directions [Fig. 5(a)]. Conversely, stroke subjects had a tendency to generate hip extension and knee extension secondary torques. Differences in these synergy patterns were not significant, presumably due to the high variability in secondary torques. Muscle activation patterns were again higher in many of the lower limb muscles in the stroke subjects when compared to the control group, where significant differences were found in adductor longus and hamstrings. The excessive activity in the adductor longus activity was surprising since this muscle opposes abduction of the leg. This co-activation of antagonistic muscle groups was consistent across subjects and most directions (see Section III-C).

During maximal hip adduction exertions, both groups tended to generate hip flexion, hip external rotation, and knee flexion secondary torques. There were no differences in the magnitude of the secondary torques between groups. There were trends for muscle activity to be higher in most lower limb muscles with significant differences found in the rectus femoris, hamstrings, and gluteus medius.

While generating maximal knee flexion exertions, both stroke and control subjects generated simultaneous hip extension, hip adduction, and hip internal rotation secondary torques [Fig. 6(a)]. There were no significant differences in the secondary torques between groups. Interestingly, there was substantially more muscle activity in the rectus femoris in the stroke subjects despite it being a strong antagonist to knee flexion. Co-activation of antagonistic muscles are discussed in more detail in Section III-C.

During maximum knee extension exertions, both stroke and control groups generated substantial hip flexion secondary torques [Fig. 6(b)]. However, the control subjects generated simultaneous hip abduction and hip external rotation, while

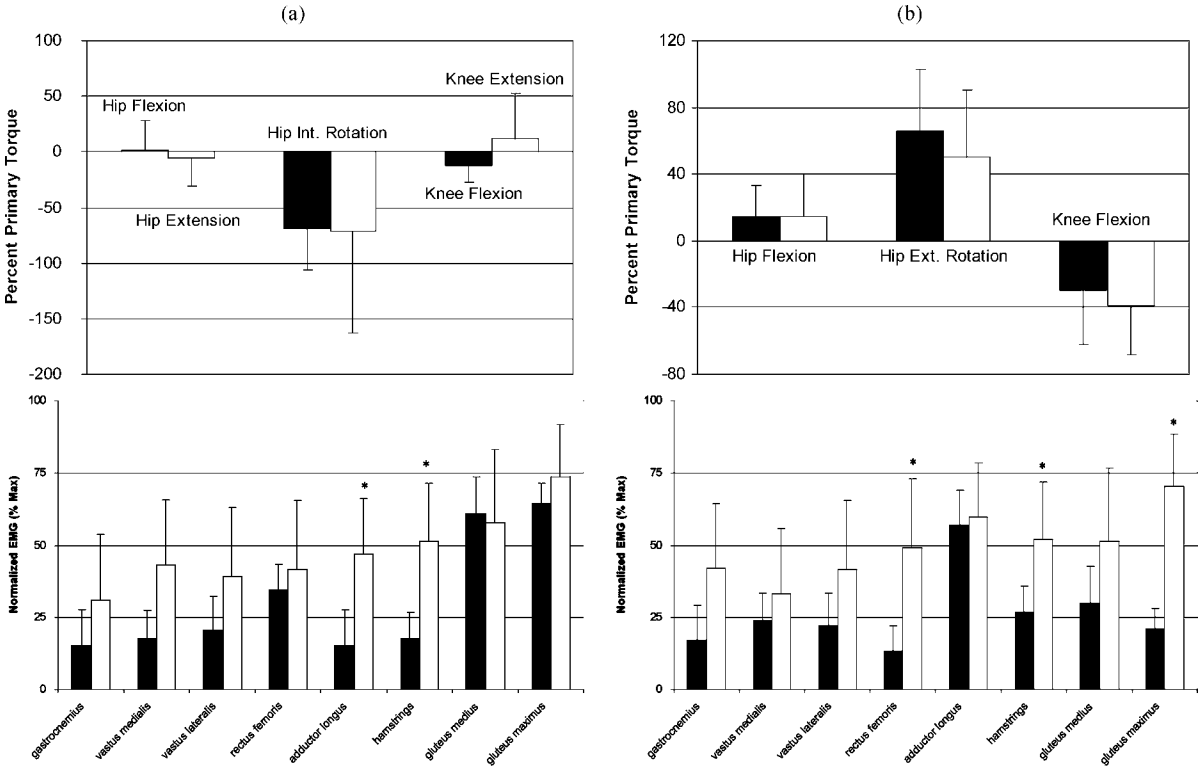

Fig. 5. Secondary torques generated during hip abduction (column a) and hip adduction (column b) along with normalized muscle activity. No significant differences were found in secondary torques for either direction. Slight differences in the extent of muscle activity were observed in some muscles, which was direction dependent. Error bars indicated 95% confidence interval. (black = control; white = stroke) ($*$ indicates $p < 0.05$).

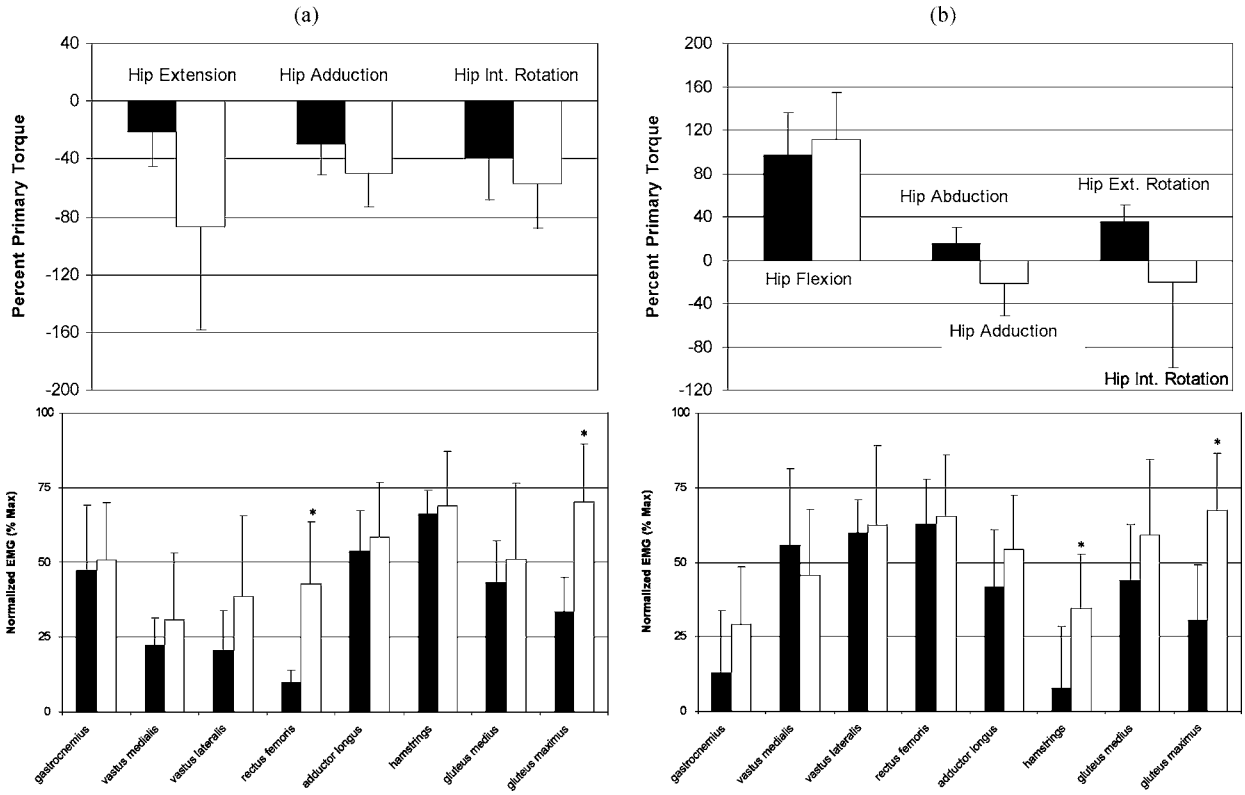

Fig. 6. Torques generated at the hip during knee flexion (column a) and extension (column b) along with normalized muscle activity at the time of the max. Similar to hip maximums, no differences in secondary torques were observed between subject groups, while some muscle activation levels were different. Error bars indicated 95% confidence interval. (black = control; white = stroke) ($*$ indicates $p < 0.05$).

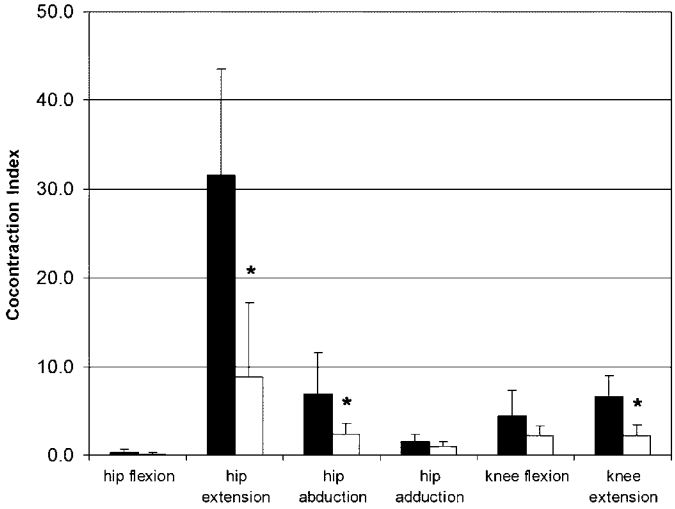

Fig. 7. Muscle co-contraction index for both groups. For hip extension, hip abduction and knee extension, stroke subjects generated significantly more muscle activity in their antagonistic muscles (lower co-contraction $\mathrm{index} = \mathrm{more}$ antagonistic activity, see text for details). $*$ indicates $p < 0.05$.

stroke subjects generated simultaneous hip adduction and hip internal rotation torques. Similar to knee flexion, stroke subjects exhibited higher muscle activity in the antagonists (e.g., hamstrings).

C. Muscle Cocontraction Index

We examined the amount of muscle co-activation during maximal exertions in both groups to determine whether observed weakness may be the result of excessive co-activation of antagonistic muscle groups. As described in Section II-E, the amount of co-activation was determined for each direction tested as the ratio of agonist activity to antagonist activity, scaled by the physiological cross sectional area of each muscle. With the exception of hip flexion, stroke subjects activated their antagonist muscles much stronger than the age-matched control subjects, as illustrated in Fig. 7. Significant differences in the co-contraction indices were found between groups for hip extension, hip abduction, and knee extension $(p < 0.05)$ while trends for differences were found in hip adduction and knee flexion. These results demonstrate that co-activation of antagonistic muscle groups during maximum isometric contractions might be at least partially responsible for the observed torque deficits described in Section II-B-1.

IV. Discussion

The results from this study demonstrate that acute stroke subjects experience profound reductions in torque generating capacity in the lower extremities, however for the most part, synergy patterns represented through concomitant secondary torques were not different than age-matched controls. The novel aspects of this experimental setup used to test strength and synergy patterns in hemiparetic stroke subjects was that subjects were in a standing posture which is similar to the posture they would be in during gait. As a result, subjects were required to maintain a certain level of balance, vestibular inputs were present, and from an experimental point of view, torques could be measured along both the intended joint of interest as well as adjacent joints and axes. In addition, because the task was isometric rather than isokinetic where reflex responses could be elicited, confounding factors such as spasticity could be minimized. Thus these tests provide detailed insight into strength and synergy patterns of hemiparetic stroke patients in a functional posture (e.g., upright standing) which advances studies that have previously looked at strength deficits at isolated joints in a seated position [1], [35].

Since the subjects tested in this study were very acute (mean time poststroke: 22 days), it is not surprising that major torque deficits in all directions tested were found. This weakness appears to be at least partially attributable to co-activation of antagonistic muscle groups, which has been found in previous studies that evaluated joint strength in isolation and in a seated position [13], [22], [24]. Other studies have reported that there were no differences in the level of co-activation in stroke subjects when compared to age-matched control subjects; however these studies tested subjects in a seated position [17], [35]. We contend that testing subjects in a standing posture increases the complexity of the task by requiring them to maintain balance and posture, perhaps revealing deficits in motor function that emerge only during functional tasks.

In the present study, subjects were asked to exert their maximal effort during isometric contractions. Kautz and Brown [11] also showed that with increased pedaling speed and therefore greater mechanical demands of the task, stroke subjects demonstrated poorly controlled muscle activation patterns. Perhaps the combination of standing test posture and the high demands of the task were sufficient to expose the poor muscle control in the stroke subjects.

While deficits in strength in the stroke subjects were not surprising, the lack of differences in secondary torques (or equivalently similar synergy patterns) was unexpected. Previous studies have demonstrated that in the upper limb of chronic stroke survivors, significant abnormal synergy patterns lead to decreases in motor function [2], [18]–[20]. These studies showed that stroke patients exhibit certain neural constraints resulting in a loss of independent joint control. For example, when subjects generate static shoulder abduction torques they also generate elbow flexion torques whereas during the generation of shoulder adduction elbow extension torques are generated in the paretic arm [18]–[20]. We did not observe similar abnormal synergy patterns despite using the same experimental approach, which could be the result of two distinct differences between the current study and previous work. First, the subjects tested here were very acute, averaging less than 30 days poststroke while the studies described above tested chronic stroke subjects (great than 1 year poststroke). It could be such that the abnormal synergy patterns had not expressed themselves so acute to the injury [12], [39]. The second key difference is that the synergies reported by [18]–[20] were in the upper limb while the focus of this work was the lower limb. Deficits in upper limb function are usually greater following stroke, which could explain the lack of differences in torque synergy patterns in our study.

Across nearly all conditions, stroke subjects activated their muscles to a larger percentage of their maximum than did the control subjects. Tang and Rymer [37] reported increased levels

of EMG activity per unit force in paretic elbow flexors compared with the nonparetic side, postulating that more motor units were needed to be recruited to achieve a particular level of force due to decreases in motor unit discharge rates. Similar results have been reported in the lower limb [40]. Elevated muscle activity would result in higher metabolic costs and consequently increase the rate of fatigue, a behavior often noted in stroke survivors.

The results in this study parallel our findings in chronic stroke subjects [34], where both acute and chronic subjects demonstrate significant weakness at least partially due to co-contracting antagonistic muscle groups, and that secondary torques are similar to controls. We expected that the excessive weakness in the acute stages of stroke would lead to abnormal synergy patterns in the chronic stages of injury, however this behavior was not found. We believe that the isometric nature of the experimental setups used in these studies simplifies the task such that perhaps these abnormal synergies are not exposed. We are currently looking at these behaviors under more complex dynamic conditions, where subjects are forced to plan and execute movement trajectories.

Our findings indicate that following acute stroke, individuals experience profound weakness in their paretic leg that is accompanied by the loss of normal muscle activation patterns. The findings that acute stroke subjects tend to co-activate their agonist-antagonist muscles to a higher degree than control subjects may be a control strategy implemented to compensate for weakness or instability.

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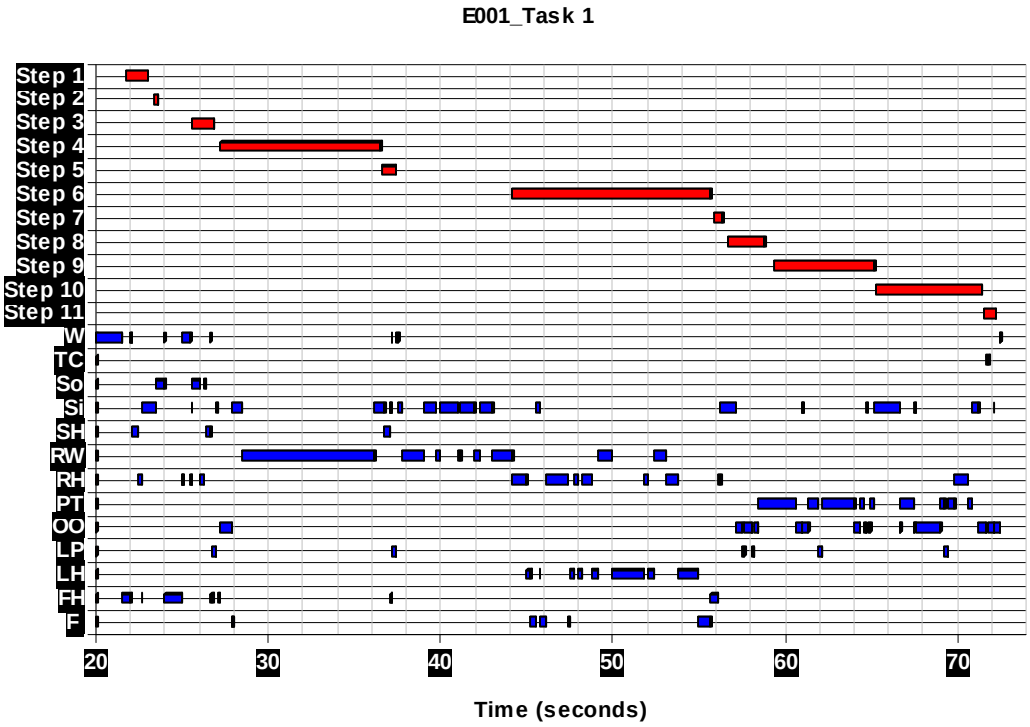
Project C1: Stroke Performance Recovery and Outcomes Study



Legend:

Task 1	Steps required to complete task.
• Window • Trashcan • Soap • Sink • Soap Holder • Running water • Right hand • Left hand • Paper towel • Faucet handle • Faucet • Other object • Lost point	1. Turn on the water 2. Rinse hands before soaping 3. Gather soap 4. Soap hands under water 5. Place soap back 6. Rinse hands after soaping 7. Turn off faucet 8. Shake water from hands 9. Gather towel 10. Dry hands 11. Throw towel away

OPENING THE "BLACK BOX" OF STROKE REHABILITATION

AND WHAT IT MEANS FOR REHABILITATION RESEARCH

The proposed editors and authors are pleased to submit their proposal for the 2005 ACRM Supplement in the *Archives of Physical Medicine & Rehabilitation*, hereafter, the *Archives* supplement. We propose a thematic supplement that seeks to tear off the cover of stroke rehabilitation's proverbial black box using the experience of an unparalleled major multi-site stroke outcomes study. The proposed supplement provides a discipline-by discipline characterization of stroke rehabilitation practice and their effects on stroke rehabilitation outcome. The supplement also examines practice variation in medications and nutrition, international variation, and the effect of excess body weight on stroke rehabilitation practice and outcome.

Equally important, and perhaps more so from the standpoint of rehabilitation research theory and practice, the proposed supplement addresses fundamental issues in rehabilitation research design and epistemology.[1] The proposed supplement will present an alternative to the research paradigm that dominates biomedical research and one that rehabilitation research has sought to emulate. We believe that the experiences of the multi-site stroke study noted above offers an approach that, in many instances, may be better suited to the multi-disciplinary and the multi-factoral nature of the rehabilitation enterprise.

The proposed editors and authors comprise a ***pre-existing team*** of investigators and clinical experts who already have a strong and abiding working relationship that bodes well for the success of the proposed supplement. This team has delivered on every aspect on one of the most demanding research protocols in rehabilitation research history. We stand ready to deliver on the proposed supplement as well.

THEME AND ITS IMPORTANCE

One of the great challenges in rehabilitation has been the ability to characterize the multi-faceted and multi-disciplinary interventions that comprise the rehabilitation process. "What does rehabilitation actually do?" one might ask. Historically, rehabilitation has tried to answer this question mainly by specifying its outcomes—enhanced function, discharge to home, participation in family and community life—instead of its processes. And rightfully so. A field needs to know first and foremost what its goals and intended outcomes are. For many years, the field presumed that by keeping its eye on the prize, i.e., the outcome, that the processes of care would self-organize to achieve the desired outcomes.

Events over the last two decades have brought increasing attention to the process of care as well as the outcome of care. First is the increased focus on practice guidelines and evidence-based practice as in the case of the AHCPR Post-stroke Practice Guideline project. Second is the increased use of non-hospital settings for rehabilitation care that has forced the question of what makes the process of care in one setting different than another. Third is the increased concern about the quality of care, i.e., the absence or presence of sentinel processes of care. Fourth is the increased scrutiny of third-party payers regarding the duration and process of care. And fifth is the inception of prospective payment for post-acute rehabilitation that has forced providers to re-examine their processes of care in order to deliver care more efficiently.

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[1] Epistemology refers to "the study or a theory of the nature and grounds of knowledge especially with reference to its limits and validity" (Merriam-Webster on-line dictionary at http://www.m-w.com/cgi-bin/dictionary.

In each of these instances, rehabilitation providers have been limited by the lack of a taxonomy to characterize rehabilitation processes, the lack of an adequate documentation system to capture what actually transpires in the treatment setting, and the lack of a research paradigm and corresponding research method that could capture the diversity and range of rehabilitation practice.

This *Archives* supplement addresses these challenges and presents an alternative approach to the research paradigms that dominate research today. We use the vehicle of a very large multi-center observational study in stroke rehabilitation to address and illustrate the challenges and alternatives that are currently available to rehabilitation research today. We do not seek to be definitive in all our observations but we do seek to illustrate how one very large data-intensive stroke rehabilitation study is managing to break through many of the barriers that have limited rehabilitation research in the past.

RELEVANCE TO ACRM'S MISSION

> " The mission of the American Congress of Rehabilitation Medicine (ACRM) is to promote the art, science, and practice of rehabilitation care for people with disabilities. This mission challenges us to be responsive to the rapidly changing environment of health care and the increasing diversity of rehabilitation service delivered by healthcare professionals from all disciplines and venues within the continuum of rehabilitation care. . . . ACRM recognizes the urgent need for an organization that will address the crucial issues of outcomes, efficacy of treatment, managed care, best practices, and reimbursement . . ."

The proposed supplement fits squarely with ACRM's mission. It addresses rehabilitation practice and uses scientific methods to understand practice variation in one rehabilitation impairment group, namely stroke survivors who comprise 20% of all inpatient rehabilitation admissions. We believe that the proposed supplement breaks new ground in rehabilitation methods and approaches and for the first time will really be able to provide a detailed characterization of stroke rehabilitation intervention.

LITERATURE REVIEW

Over the years, rehabilitation has expended enormous intellectual energy conceptualizing models of disability, identifying relevant outcome domains, and developing outcome measures, including psychometric and clinometric research on validity, reliability, scaling, and interpretation of these measures. By contrast, little energy has been expended on issues related to the *processes* of care and interventions used in rehabilitation. The *input side* (patient, treatment, and environment characteristics) has not been subjected to the same level of conceptual and methodologic rigor as the *output side* in the effectiveness equation: There has been little systematic disaggregation (conceptualizing, measuring, and counting) of interventions used in rehabilitation. While there is research of individual treatments, focusing on their effectiveness either as "stand alone" interventions in an outpatient setting or as part of a larger package of inpatient or outpatient services, there is little research that investigates the contribution of all individual components of a rehabilitation program to the outcomes, individually and combined.

Typically, outcomes research or effectiveness research has examined "unopened" packages of services, gross settings of care, or organizational milieus (e.g., rehabilitation team culture). Most previous studies have examined rehabilitation in the aggregate; investigators have looked at rehabilitation as a whole, such as comparing outcomes of patients treated in hospital rehabilitation centers versus those treated in skilled nursing facilities.[2,3] Quantifying the amount of therapy that a patient receives usually does not go beyond length of stay or hours of each type of therapy delivered.[4,5,6] Rarely are individual interventions examined in the context of the entire array of interdisciplinary interventions used and within the structural arrangements (such as care settings) in which care is delivered. In the case of stroke rehabilitation, for example, no study has investigated the effects of multiple aspects of stroke rehabilitation simultaneously, although some explorations of the effects of structural and process characteristics of the treatment environment have been published.[7,8,9,10] In short, we have yet to disassemble the "black box" of rehabilitation.

As a result of our failure to disaggregate, we cannot identify those interventions that truly contribute to rehabilitation outcomes. Even if we could distinguish the "active ingredients" in rehabilitation, we would still need to quantify them, which depends on adequate measurement. Each intervention presents its own

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[9] Hoenig H, Sloane R, Horner RD, Zolkewitz M, Reker D. Differences in rehabilitation services and outcomes among stroke patients cared for in veterans hospitals. *Health Serv Res.* 2001 Feb;35(6):1293-318.

[10] Duncan PW, Horner RD, Reker DM, Samsa GP, Hoenig H, Hamilton B, LaClair BJ, Dudley TK. Adherence to postacute rehabilitation guidelines is associated with functional recovery in stroke. *Stroke.* 2002 Jan;33(1):167-77.

measurement challenge and rehabilitation interventions often are not mutually exclusive. For example, a physical therapist may combine motor learning strategies with balance training while working with a patient on sit-to-stand activities. Both are important related components of therapy and sometimes difficult to differentiate. Separating the effects of individual interventions and their multiple interactions is an analytical and statistical challenge. Rehabilitation practitioners claim that rehabilitation is an interdisciplinary process that is more than the sum of its parts. That may be the case, but without identifying and measuring the parts, we cannot begin to evaluate the whole. Some parts may not be necessary, or can be substituted for one another. Optimal interventions may be different for various diagnoses, admission functional levels, or co-morbidities.

Several have called for a taxonomy of treatments that will bring greater clarity and more precision to describing and quantifying what happens in the rehabilitation process, and thus serve as the basis for measuring interventions used in conjunction with outcomes.[11] [12] [13] [14] [15] In fact, the matter of a taxonomy of rehabilitation interventions has been the subject of many recent conversations in rehabilitation research especially within the ACRM as noted by the vigorous discussions of the ACRM Task Force on Rehabilitation Taxonomy. Some have labeled this extended conversation as a rehabilitation zeitgeist. The proposed supplement is not primarily about rehabilitation taxonomy development, however. That is the subject of another soon-to-be-published paper that emerged from the study that motivates this proposal. The proposed supplement does report on how a stroke rehabilitation taxonomy became an inevitable byproduct of the attempt to identify more clearly and precisely the interventions that comprise the stroke rehabilitation process (Paper 3). It certainly is not the only taxonomy—and a different taxonomy might emerge using a different level of resolution. Nonetheless, the taxonomy used in this supplement is one developed by many clinicians working within and across disciplines with colleagues and researchers from several different sites.

Armed with a workable taxonomy, one can begin to examine what actually transpires in the rehabilitation process—within disciplines, across disciplines, and across sites of care. Studies suggest that there is large variation in stroke rehabilitation practice.[16] [17] [18] [19] [20] [21] [22] [23] [24] [25] There is also variation practice between countries.[26] [27] [28] Unfortunately, many of these studies report on only one domain of therapy, such

[11] Dijkers MP. A taxonomy of rehabilitation interventions: Feasibility and development suggestions. Presentation at the 2001 annual meetings of the American Congress of Rehabilitation Medicine, Tucson, AZ, October 25-28, 2001.

[12] Dijkers, MP. ACRM presentation in October 2003

[13] Hart, T. ACRM presentation in October 2003 and presentation to the NIH National Advisory Board on Medical Rehabilitation Research in December 2003.

[14] Whyte J, Hart T. It's more than a black box; it's a Russian doll: Defining rehabilitation treatments. *Am J Phys Med Rehabil* 20003; 82:639-652.

[15] DeJong G, Horn S, Gassaway J, Dijkers M, Slavin S. Toward a taxonomy of rehabilitation interventions: using an inductive approach to examine the 'black box' of rehabilitation. *Archives of Physical Medicine & Rehabilitation* (in press), 2004.

[16] Kwan J, Sandercock P. In-hospital care pathways for stroke: a Cochrane systematic review. *Stroke* 2003; 34: 587-8.

as gait training or activities of daily living (ADL).[29] Rarely do studies examine the full range of therapeutic interventions simultaneously.

The multi-factorial character of rehabilitation interventions has proved daunting in rehabilitation research. Building on our introductory observations and at the risk of oversimplification, one can characterize rehabilitation effectiveness or outcomes research as existing along a continuum. At one end of the continuum, rehabilitation research attempts to compare bundled packages of services without differentiating the content of the package. As noted earlier, a classic comparison is the comparison between the outcomes of rehabilitation care in skilled nursing facilities (SNF) versus care provided in inpatient rehabilitation facilities (IRFs). No clear differentiation of individual therapies is made at this aggregate level of analysis. At the other end of the continuum, rehabilitation research attempts to examine the efficacy of a single intervention (or closely but limited array of interventions) compared to another single intervention or to placebo or sham intervention as in the case of a randomized controlled trial (RCT).

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[17] Jette D, Smout R, James R, Gassaway J, Horn S. (unpublished manuscript). Physical therapy interventions for patients with stroke in an acute rehabilitation setting.

[18] Hoenig H, Duncan PW, Horner RD et al. Structure, process, and outcomes in stroke rehabilitation. *Med Care* 2002; 40: 1036-47.

[19] Duncan P, Richards L, Wallace D et al. A Randomized, Controlled Pilot Study of a Home-Based Exercise Program for Individuals With Mild and Moderate Stroke. *Stroke* 1998; 29: 2055-2060.

[20] Walker M, Drummond JG, Sackley C. Occupational therapy for stroke patients: A survey of current practice. *British Journal of Occupational Therapy* 2000; 63: 367-372.

[21] Sackley CM, Lincoln N. Physiotherapy treatment for stroke patients: A survey of current practice. *Physiotherapy Theory and Practice* 1996; **12**: 87-96.

[22] Duncan P, Studenski S, Richards CL et al. A Randomized Clinical Trial of Therapeutic Exercise in Sub-Acute Stroke. in press.

[23] Ballinger C, Ashburn A, Low J, Roderick P. Unpacking the black box of therapy -- a pilot study to describe occupational therapy and physiotherapy interventions for people with stroke. *Clin Rehabil* 1999; 13: 301-9.

[24] Snels I, Beckerman H, Lankhorst GJ, Bouter L. Treatment of hemiplegic shoulder pain in the Netherlands: results of a national survey. *Clin Rehabil* 2000; 14: 20-7.

[25] Rothi L. A reminiscence of the first two years, current practice, and a renewal of our purpose. *Invited presentation at the Academy of Neurologic Communication Disorders and Sciences*. Washington, DC, 2000.

[26] Ogiwara S. Physiotherapy in stroke rehabilitation: a comparison of bases for treatment between Japan and Sweden. *Journal of Physical Therapy* 1997; 9: 63-69.

[27] Nilsson L, Nordholm LA. Physical therapy in stroke rehabilitation: bases for Swedish physiotherapists' choice of treatment. *Physiotherapy Theory and Practice* 1992; 8: 49-55.

[28] Lennon S. Physiotherapy practice in stroke rehabilitation: a survey. *Disabil Rehabil* 2003; 25: 455-61.

[29] Booth J, Davidson I, Winstanley J, Waters K. Observing washing and dressing of stroke patients: nursing intervention compared with occupational therapists. What is the difference? *J Adv Nurs* 2001; 33: 98-105.

The proposed supplement will argue that this dichotomy, at one level, presents a false choice—a choice made necessary in the absence of a taxonomy that can adequately characterize rehabilitation care. Yes, there have been studies that have been conducted near the middle of this continuum as in studies that examine the differential effects of hours of physical or occupational therapy affect outcome. In the final analysis, this middle-ground type of study remains inherently unsatisfying because it does not characterize what therapists in fact do during the therapy encounter. Single-bullet RCTs also remain unsatisfying due to their logistical challenges and the opportunity for generalization. More importantly, there simply is not enough money in the nation's entire biomedical research budget to examine all the variation of practice in rehabilitation care.

The proposed supplement presents an alternative to this false-choice state of affairs. We do not deny the important role that other types of research can have but we believe that rehabilitation research has not taken full advantage of multivariate statistical approaches that can power today's observational studies. With the aid of a taxonomy, large clinical databases, and partnering with front-line clinicians, researchers can finally address some of the methodological limitations that have bedeviled rehabilitation research all of these years. We do not suggest that the evidence resulting from our research is necessarily definitive. "[O]ne . . . feature of medical evidence is its inherently provisional nature. . . [E]vidence is emergent and therefore expected to change with time."[30]

Objectives

In short, the proposed supplement has several objectives:

1. Addresses some of the larger epistemological issues in rehabilitation and biomedical research (Paper 2);

2. Introduces the concept of a clinical practice improvement (CPI) study and where it fits in the pantheon of rehabilitation research (Paper 2);

3. Describes how a CPI approach has been operationalized and applied in a multi-site stroke rehabilitation study (Paper 3);

4. Uses CPI to characterize rehabilitation practice and practice variation and explain rehabilitation outcomes (Papers 4-8);

5. Explain the impact of the IRF-PPS on stroke rehabilitation practice using the study's ability to actually characterize rehabilitation practice (Paper 9);

6. Apply CPI to help understand the role of obesity in stroke rehabilitation practice and outcome (Paper 10);

7. Characterize some international differences in stroke rehabilitation practice and their differential effects on outcomes (Paper 11); and

8. Determine the extent to which rehabilitation practices that affect outcomes at discharge also affect longer-term 6-month outcomes (Paper 11).

[30] Ross EG. Seven characteristics of medical evidence. *J Evaluation in Clinical Practice* 2000; 6: 2, 93-97.

The proposed supplement concludes with brief commentaries from several leaders in the field of rehabilitation and stroke rehabilitation who can address the epistemologic, methodologic, clinical, and policy issues raised by the 11 papers presented in the supplement.

INTENDED AUDIENCE

This supplement addresses fundamental issues of concern to all ACRM and rehabilitation stakeholders—researchers, providers, large purchasers, and payers—who are concerned with issues related to evidence-based practice in stroke rehabilitation. It is not designed to address the decision needs of consumers although it will address issues facing consumers who may want to understand the nature of evidence-based practice and how it can help inform their choices about rehabilitation alternatives.

Content

1. **Gerben DeJong, Brendan Conroy, Edward Healton, Susan Horn.** "Introduction to this *Archives Supplement*." 3 published pages

This will be a brief overview of purpose and scope of the supplement and how the supplement unfolds from paper to paper. This article will also reference our earlier previously in-press work on stroke rehabilitation taxonomy.

2. **Susan Horn, Gerben DeJong, David Ryser, Peter Veazie, Jeff Teraoka, *et al.*** "Another Look at Observational Studies in Rehabilitation Research: Going Beyond the Holy Grail of the Randomized Controlled Trial." [This is a more theoretical paper]. 12 published pages.

The randomized controlled trial (RCT) is considered the gold standard in bio-medical research. It is held as the highest level of evidence for efficacy and best practice or what Miettinen calls "all purpose RCTism."[31] The RCT is, unfortunately, an expensive and unwieldy, if not clumsy, tool for discovering and establishing best practice in rehabilitation. RCTs work well when the intervention is singular, the timing is well established, and the dosage is fairly clear. RCTs do not work as well with rehabilitation where the interventions are multi-faceted and multidisciplinary, where timing is in doubt, and the dosage will have to vary with patient tolerance and other factors. In short, RCTs do not lend themselves well to black-box research. There simply is not enough money in the biomedical research world to subject all the variations of rehabilitation practice to an endless array of RCTs. In the interim, we have to rely more on observational studies that are more naturalistic and where the interventions are not as contrived for experimental purposes. Many argue that observational cohort studies are well down the hierarchy of scientific evidence. This paper challenges this assumption by introducing the concept of a clinical practice improvement (CPI) study. One of the strengths of CPI studies is its attention to defining and characterizing the black box of clinical practice. One downside is that CPI studies require demanding data collection protocols but the upside is that they offer the one of the best opportunities to uncover best practices more quickly and still achieve many of the advantages that RCTs are presumed to have. The paper juxtaposes RCT and CPI approaches, evaluates their relative advantages and disadvantages, and discusses their implications for rehabilitation research and evidence-based practice.

[31] Miettinen O. Commentary on Gupta. *J of Evaluation in Clinical Practice* 2003; 9:123-127.

3. **Julie Gassaway, Susan Horn, Crystal Clark, Mary Slavin, and other interested parties.** "Applying the CPI approach to Stroke Rehabilitation: Methods Used to Define and Evaluate the Black Box of Stroke Rehabilitation." 10 published pages.

This paper provides an introduction to the research methods used in the Post-stroke Rehabilitation Outcome Project. It discusses how the CPI approach was operationalized in the case of a multi-site stroke rehabilitation outcomes study, the results of which are discussed in subsequent papers. One of the singular contributions of the PSROP has been its attention to defining and measuring the interventions used in stroke rehabilitation, i.e., characterizing the interventions in the proverbial black box. The study attempted to address not only the variation in practice but also the variation in language and vocabulary the study uncovered when it attempted to describe stroke rehabilitation practice. The paper also describes the project's clinical sites, study population, the participation of clinicians in identifying practice parameters, the data collection protocols, and the database that is the basis for the papers that follow.

Note: There is one combined abstract for Papers 4, 5, & 6. See bullet following Paper 6.

4. **Diane Jette, Randal Smout, Nancy Latham, Gerben DeJong, Diane Nichols, Jaime Lees, Adam Procino, Brad Zollinger, Shelley Howe, Murray Brandstater, Marti Carroll, *et al.*** "Characterizing Physical Therapy Practice in Stroke Rehabilitation. 8 published pages.

5. **Nancy Latham, Randal Smout, Diane Jette, Lori Richards, Cathy Goodman, Lauren Rosenberg, Heather Welch, Murray Brandstater, Gerben DeJong, *et al.*** "Characterizing Occupational Therapy Practice in Stroke Rehabilitation." 8 published pages.

6. **Brook Hatfield, Randal Smout, Janice Coles, Debbie Millet, Joyce Maughn, Andrew Dodds, *et al.*** "Characterizing Speech and Language Therapy in Stroke Rehabilitation." 8 published pages.

- There is currently little research to describe the specific therapy interventions that are used in stroke rehabilitation, and how the use of these interventions changes over a rehabilitation episode. Most studies to date have included only gross descriptions of stroke therapy interventions, such as the minutes of therapy provided by each profession. Our ability to describe specific physical therapy (PT), occupational therapy (OT) and speech language pathology (SLP) interventions has been hampered by the lack of clear definitions of therapy interventions. To overcome this problem, a taxonomy of interventions used in PT, OT and SLP was created for the Post Stroke Rehabilitation Outcomes Project (PSROP). The PSROP provides enormous detail about the treatments and therapeutic activities that therapists used throughout the entire length of stay on a rehabilitation unit. The aim of these three papers is to describe the interventions that were used by PT, OT and SLP and to describe how these interventions changed during the initial, middle and final third of each patient's therapy episode. The analyses for these three papers will be carried out in parallel, to allow comparisons about how the nature of the interventions, including the type of activities, the duration of the sessions and the frequency that each intervention was selected varies over time and across the therapy professions. These papers will provide information about the specific interventions and activities that PT's, OT's and SLP's use in stroke rehabilitation with more detail and precision than any previous publications.

7. **Brendan Conroy, Richard Zorowitz, Susan Horn, Jeff Teraoka, Jim Young, David Ryser, Sarah Maulden, Andrew Dodds, Jeff Randle, *et al.*.** "Variation in Use of Medications in Stroke Rehabilitation." 8 published pages.

The PSROP uncovered significant variation in the use of medications from one clinical site to another that cannot be explained due to patient differences but to differences in physician preferences (that may also be shaped by drug formularies and other factors). There appears to be wide variation in outcome associated with variation in medication use and this paper explores the associations between drug therapy and outcomes and its implications for practice and future validation studies.

8. **Sarah Maulden, Randy Smout, Susan Horn, *et al.*.** "Nutrition as a Rehabilitation Intervention." 8 published pages.

Malnutrition's association with poor outcomes was reported as far back as 1936.[32] Hospital associated malnutrition was reported in the middle and late 1970's.[33] [34] Early enteral feeding in trauma patients has been espoused for nearly two decades. Traditional rehabilitation therapies require much time and effort by stroke patients who often have attendant swallowing difficulties. Nutrition is rarely regarded as a rehabilitation intervention. Yet, we observed that nutritional support varied greatly from patient to patient and from site to site. This paper characterizes differences in the timing and the amount of nutritional intake and their relationship to intensiveness of therapy and rehabilitation outcomes.

9. **Gerben DeJong, David Ryser, John Melvin, Susan Horn, *et al.*** "The Impact of the Inpatient Rehabilitation Facility Prospective Payment System (IRF-PPS) on Stroke Rehabilitation Practice." 9 published pages.

The PSROP was conducted over a 3-year period from 2001-2003, a period that predates and postdates the implementation of the IRF-PPS in 2002. We were able to observe significant differences in practice patterns including changes in lengths of stay. More importantly, we are able to observe very specifically how PPS affected the mix, intensity, and duration of individual therapies. In short, this paper reports on how PPS has reshaped the black box of stroke rehabilitation.

10. **Crystal Clark *et al.*** "The Effect of Body Weight on Rehabilitation Practice and Outcomes." 8 published pages.

Recent studies have clarified the relationship between obesity and stroke. While the relationship between obesity and coronary artery disease, diabetes, and hypertension have been well established, the evidence establishing obesity as an independent risk factor for stroke has only recently been established. Abdominal obesity appears to predict the risk of stroke in men and obesity and weight gain appear to be risk factors for ischemic stroke in women.[35] As obesity's independent role in stroke has come to light, there appears to be a need for basic statistics on the prevalence of obesity in stroke patients, its impact on rehabilitation practice, and its effect on rehabilitation outcomes.

This paper provides bodyweight and/or body mass index (BMI) on over 750 stroke patients enrolled in the Post Stroke Rehabilitation Outcomes Project (PSROP). The PSROP enrolled over 1218 patients from 7 clinical sites of diverse geographic

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[32] Studley HO. Percentage of weight loss: a basic indicator of surgical risk in patients with chronic peptic ulcer. *JAMA* 1936: 106:458-60.

[33] Weinsier RL, Hunker EM, Krumdieck CL, Butterworth CE. Hospital malnutrition: a prospective evaluation of general medical patients during the course of hospitalization. *Am. J. Clin. Nutr*. 1979; 32:418-26.

[34] Bistrian, BR, Blackburn GL, Vitale J, Cochran D, Naylor J. Prevalence of malnutrition in general medical patients. *JAMA* 1976; 235:1567-70.

[35] Seung-Han S. Abdominal obesity and risk of ischemic stroke. *Stroke* 2003; 34:1586-1592.

representation to gather information on the critical patient, provider, and process elements associated with optimal outcomes in post-stroke rehabilitation. To date, the evidence linking bodyweight to rehabilitation outcomes has been primarily limited to cardiopulmonary rehabilitation and therapy following orthopedic procedures. In these areas a higher BMI was associated with relative quadriceps weakness which impacts on patient-level outcomes.[36] Using bivariate and multivariate analyses, we examine the impact of bodyweight and/or BMI on care processes and practices, as well as selected outcomes (length of stay, FIM, complications, and discharge location) in this multi-site rehabilitation study.

11. **Harry McNaughton, Gerben DeJong, Nancy Latham, Phillip Beatty, Melinda Neri, John Melvin, Murray Brandstater, *et al.*.** "International Variation in Stroke Rehabilitation Practice and their Impact on Short- and Long-term Outcomes." 10 published pages.

One of the PSROP's 7 clinical sites is in New Zealand. The study uncovered significant differences in practice patterns between the New Zealand site and the 6 American sites. One strength of the CPI approach—compared to RCTs, for example—is its ability to uncover and accommodate wide practice variation. This paper makes 2 sets of comparisons: The first compares NZ with the U.S. centers combined making adjustments for case-mix differences; the second compares NZ with one of the U.S. centers that also obtained 6-month outcome data. The paper describes variation in case mix, practice patterns, and outcomes. The New Zealand site is also one of two sites in the study that acquired data on 6-month outcomes. Hence, the paper also examines the impact on longer-term outcomes that relate to activity and participation. We may decide to make the matter of longer-term outcomes a separate paper.

12. **John Melvin, Edward Healton, Pamela Duncan, Alan Jette, *et al.*** "Commentary." 2 published pages for each commentary. (Unlike the papers listed above, the proposed commentators are examples of the kinds of expertise we wish to invite as potential commentators.)

This portion of the supplement will include a series of short commentaries by experts in the field. The commentaries will be preceded by a short summary of the papers' sentinel findings and their collective implications for rehabilitation research, practice, and policy.

Qualifications of Guest Editors

The three proposed editors have worked together intensely over the last 4 years in developing the Post-stroke Rehabilitation Outcomes Project (PSROP) and have collaborated on several manuscripts that are now finding their way into the literature. They enjoy a high degree of mutual trust and sharing of responsibility. Dr. DeJong and Dr. Horn had a previous

[36] Silva M. Knee strength after total knee arthroplasty. *J Arthroplasy* 2003 Aug; 18(5): 605-11.

professional relationship more than 20 years ago. Drs. DeJong and Horn are experienced writers and editors; Dr. Conroy's strengths are in editing.

Gerben DeJong, PhD is the Associate Director for Health Policy & Health Services Research with the University of Florida Brooks Center for Rehabilitation Studies. He also serves as a professor in the Department of Health Services Administration within the University of Florida's College of Health Professions and concurrently serves as a Senior Fellow with the NRH Neuroscience Research Center. Prior to coming to the University of Florida in 2002, Dr. DeJong served for 16 years (1985-2001) as the Director of Research for the National Rehabilitation Hospital (NRH) in Washington, DC and as the Founding Director of hospital's Center for Health & Disability Research located in the MedStar Research Institute. While at NRH, he served as a professor in the Department of Family Medicine at Georgetown University. From 2001-2002, Dr. DeJong served as a Senior Fellow with the NRH Center for Health and Disability Research while based in Prague in the Czech Republic. During his tenure with NRH and the MedStar Research Institute, Dr. DeJong also served as the Co-director of the federally funded Research and Training Center (RTC) on Managed Care & Disability (1997-2002) and previously served as the Director of the RTC on Medical Rehabilitation and Health Policy (1993-97). Dr. DeJong's academic training is in economics and public policy studies (MA and MPA, University of Michigan; PhD, Brandeis University). His main research interests are in health outcomes, health care utilization, health payment policy, evidence-based practice in rehabilitation, disability policy, income maintenance policy, and national health policy. He is the author or co-author of more than 200 papers on health, income maintenance, disability, and medical rehabilitation.

Susan D. Horn, PhD is Senior Scientist with the Institute for Clinical Outcomes Research (ICOR) and Vice President for research for International Severity Information Systems, Inc. (ISIS), and Adjunct Professor in the Department of Medical Informatics at the University of Utah School of Medicine in Salt Lake City. From 1968-1991, Dr. Horn was a full-time faculty member at The Johns Hopkins University in Baltimore, Maryland. From 1991-1995, she was senior scientist at Intermountain Health Care in Salt Lake City. In 1982, Dr. Horn and colleagues began developing the Comprehensive Severity Index (CSI®), with inpatient, ambulatory, hospice, rehabilitation, and long-term care components for adult and pediatric patients. CSI software collects disease-specific, physiologic severity data for Clinical Practice Improvement (CPI) and risk-adjusted outcomes. Dr. Horn has conducted CPI projects in cost-containment practices in HMOs, pediatric severity of illness, asthma, and bronchiolitis, GI surgery, congestive heart failure, pressure ulcers in long-term-care, ambulatory diabetes, hospice, post-stroke rehabilitation, falls, and women's health. She has authored over 140 publications on statistical methods, health services research, severity measurement, clinical practice improvement, and quality of care. Dr. Horn edited *Clinical Practice Improvement Methodology: Implementation and Evaluation*, 1997. She is the PI for the NIDRR-funded Post-Stroke Rehabilitation Outcomes Project that is addressing the need for scientific data supporting the effectiveness of rehabilitation treatments. Dr. Horn earned a B.A. in mathematics at Cornell University and a Ph.D. in statistics at Stanford University.

Brendan Conroy, MD has been intimately involved in the development and management of the Post-Stroke Rehabilitation Outcomes Project (PSROP) since its inception. He has been the Medical Director of the

National Rehabilitation Hospital's Stroke Rehabilitation Program since January of 1998. He is Board Certified in Physical Medicine and Rehabilitation. He has been involved in several other stroke rehabilitation research projects on the use of medications and natural substances, the provision of rehabilitation services using telemedicine technology, and the use of robotics in stroke rehabilitation (e.g., Lokomat/Robotic Gait Training, self-powered Self Range of Motion for plegic arms). He has authored several published papers and chapters.

Qualifications of contributing authors

See **Appendix A** for an alphabetical listing of individual author bios. See **Appendix B** for letters of commitment from individuals authors. Some bios and letters of commitment are not included.

ACTION PLAN: PROJECT TEAM, PROPOSED CONFERENCE, TIMETABLE, AND FUNDING (FEASIBILITY AND PROBABILITY OF SUCCESS)

Project Team

The proposed editors and nearly all of the proposed authors have worked together as a project team for 3 or more years under the auspices of the Post-stroke Rehabilitation Outcome Project (PSROP) cited earlier. Some of the proposed authors joined the project team somewhat later in its history but all are committed to its success and the publication of its findings. The overall Project Team meets each Friday morning via conference call and subteams of clinicians and investigators meet on an as-needed basis. We propose to continue the weekly conference calls for the Project Team as a whole and propose additional as-needed teams for select topics. True to the ACRM spirit of interdisciplinary rehabilitation, the Project Team, i.e., the proposed authors, consists of physicians, therapists, nurses, and others from each of the 7 stroke rehabilitation sites and an array of several other investigators who have gravitated toward the project over time. The PSROP has succeeded in fostering ownership and commitment among Project Team members, the individual clinical sites, and among proposed authors that bode well for the success of the proposed supplement.

The proposed authors met as a group in Washington, DC this past July to map out potential papers, possible authors, and subteams to work on individuals papers.

Funding & sponsorship

The original PSROP was funded under the auspices of a NIDRR-funded project as part of the Rehabilitation Research and Training Center on Medical Rehabilitation Outcomes at Boston University's Sargent College (PI: A Jette, PhD) with subcontracts to the Institute on Clinical Outcomes Research (ICOR) (S Horn, PhD) and the National Rehabilitation Hospital Center for Health & Disability Research (G DeJong). The NRH group was fortunate to obtain supplemental funding for the project from the National Blue Cross Blue Shield Association and through the NRH Neuroscience Research Center with a grant from the Department of Defense funded under a cooperative agreement with the U.S. Army & Materiel Command (Cooperative Agreement Award # DAMD17-02-2-0032, Cheryl R. Miles, project officer).

The NRH Neuroscience Center has agreed to sponsor a national conference in late 2004 or in 2005 that will feature the papers proposed here. The NRH Neuroscience Center will support Dr. Conroy's participation in this effort and Dr. DeJong's editorial role under a subcontract to the University of Florida Brooks Center for Rehabilitation Studies. The NRH Neuroscience Center will also provide a limited support to ICOR to conduct additional analyses pursuant to the preparation of the proposed papers. Because of NRH's overall financial support for the supplement under the auspices of its Neuroscience Research Center and the conference tie-in, it will be identified as a sponsor for the supplement. If ACRM and the *Archives* approve our application, we will also seek support from two other organizations—a federal source and a private one that will remain unmentioned for now. We believe that the proposed financial backing for the proposed supplement will help to ensure the success of the proposed supplement.

Timetable

The ACRM RFP already provides the timeline for the external review that will commence in February 2005 but leaves it to the proposed editor(s) to specify the timeline for February 1, 2004 to 2005. Figure 1 outlines our proposed timeline for this period.

Task	Feb 2004	Mar 2004	Apr 2004	May 2004	June 2004	Jul 2004	Aug 2004	Sept 2004	Oct 2004	Nov 2004	Dec 2004	Jan 2005	Feb 2005
Guest editors notify authors													
Editors send out author guidelines													
Authors provide written commitment													
Editors recruit potential reviewers													
Authors submit first drafts (staggered)													
Editors send manuscripts for internal rev													
Reviewers rate & return first drafts													
Authors prepare second draft													
Editors edit second draft													
Editors submit manuscript for external rev													

Timeline

ORIGINAL ARTICLE

Opening the Black Box of Poststroke Rehabilitation: Stroke Rehabilitation Patients, Processes, and Outcomes

Gerben DeJong, PhD, Susan D. Horn, PhD, Brendan Conroy, MD, Diane Nichols, PT, NCS, Edward B. Healton, MD, MPH

ABSTRACT. DeJong G, Horn SD, Conroy B, Nichols D, Healton EB. Opening the black box of poststroke rehabilitation: stroke rehabilitation patients, processes, and outcomes. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S1-7.

This article introduces the journal's supplement devoted to the methods and findings of the 7-site Post-Stroke Rehabilitation Outcomes Project (PSROP), a study designed to provide a very granular in-depth understanding of stroke rehabilitation practice and how practice is related to outcomes. The article summarizes current knowledge about the effectiveness of post-stroke rehabilitation, outlines where the PSROP fits into the broader traditions of stroke rehabilitation outcomes research, underscores the study's methodologic innovations, and summarizes the scope of the articles that follow.

Key Words: Intervention studies; Rehabilitation; Stroke; Treatment outcome.

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THIS *ARCHIVES* SUPPLEMENT reports on the Post-Stroke Rehabilitation Outcomes Project (PSROP), a large, multicenter stroke rehabilitation study that entailed the collaboration of 7 hospital-based rehabilitation centers—6 in the United States and 1 in New Zealand. These 7 centers enrolled nearly 1400 stroke rehabilitation patients from 2001 to 2003. The study's database (N=1291) provides an in-depth view of inpatient rehabilitation practice. This supplement reports on the motivation for the study, its methods, and findings across several dimensions of practice. This supplement also addresses important epistemologic issues in rehabilitation research that are raised by the methods and findings of the PSROP.

Stroke remains among the most compelling public health issues in the world today. In the United States alone, an estimated 700,000 people experience a new or recurrent stroke each year.[1] Approximately one quarter of these people die, and a significant portion of the remainder survive with long-term disability. There are approximately 4.8 million stroke survivors in the population, and about 1.1 million of these report having functional limitations. In economic terms, the estimated direct and indirect costs of stroke are $56.8 billion per year, as of 2005.[1,2]

Stroke survivors account for about 17% of all inpatient rehabilitation admissions. Although lengths of stay (LOSs) in rehabilitation settings have diminished considerably over the last few decades, rehabilitation remains an extended and labor-intensive affair that has seen few major breakthroughs. Much of what we do in stroke rehabilitation may be routine, but much also remains a trial-and-error matter that is difficult to characterize. Rehabilitation practitioners, it is said, customize their interventions to each individual patient. One result is that stroke rehabilitation practice varies from one patient to another and from one rehabilitation center to another and thus often lacks the standardization that is being demanded in other areas of medical practice, as evidenced by the development of practice guidelines and standardized protocols. In other words, stroke rehabilitation remains a "black box" of sorts. We have good ways of characterizing what goes into the black box (ie, the patient) and what comes out (ie, the patient) but little notion of how best to characterize what goes on inside the black box. Our failure to do so also limits our ability to know exactly what the active ingredients are in the rehabilitation process that are supposed to shape patient outcomes. This lack of specificity also limits the claims that providers and consumers can make of health plans and government to secure the financial resources needed for stroke rehabilitation.

CURRENT KNOWLEDGE OF THE EFFECTIVENESS OF POSTSTROKE REHABILITATION

Stroke survivors constitute one of the largest consumer groups of postacute rehabilitation services in the American health care system.[3] Among inpatient rehabilitation facilities (IRFs), industry data for 2004 indicate that the average Medicare reimbursement per day for a stroke survivor is about $1050 and that the average LOS is 17.3 days. In this age of continuous quality improvement, cost containment, reimbursement reduction, and the drive for evidence-based practice (EBP), rehabilitation providers are obligated to make sure what they are doing is clinically effective, cost efficient, and supported by data. Despite the large body of stroke rehabilitation research, the truth is that we do not know exactly how the $1050 per day is spent. Medicare and sundry health plans remain willing for the moment to provide the funding for stroke rehabilitation.

Of the more than 700,000 people who experience a stroke each year,[4] about 300,000 to 400,000 will need some rehabilitation services.[5] These stroke survivors will be assessed and given initial rehabilitation treatments while in acute care; will be screened by a representative of a rehabilitation facility, both for clinical need and financial support availability; and then will be transferred or discharged to one of any of the following: a free-standing rehabilitation hospital, a rehabilitation unit located in an acute care hospital, a skilled nursing facility (SNF) for subacute rehabilitation, a nursing home for residential ac-

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commodations and care, or to home for care by family and to receive rehabilitation services either at home or as an outpatient. If the survivor goes to a hospital-based rehabilitation center—now commonly referred to as an IRF, he/she will receive an ongoing therapeutic program that consists of round-the-clock rehabilitation nursing and physician coverage; daily physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP); and possibly additional services from psychology, social work, therapeutic recreation, vocational rehabilitation, and rehabilitation engineering staffs. In addition, stroke rehabilitation patients will have access to medical consultants of all possible types, specialist nurses such as those for skin and ostomy care, chaplains, family members, legal representatives, insurance company case managers, and research investigators and their assistants.

The interaction between each stroke survivor, his/her comorbidities, personal behaviors, and coping ability and all of these health care providers and family members is complex and highly specific—with each and all factors having a possible impact on a patient's outcome. The interaction of the patient with the facility's system of care comprises the process of care that heretofore has not been systematically disaggregated, measured, and evaluated to determine the most active ingredients that affect patient outcomes.

The following is a far-from-exhaustive review of some important research findings about stroke rehabilitation in IRFs. In 1982, Lind[6] reviewed the 7 best studies on the effectiveness of inpatient stroke rehabilitation. The results of these observational studies were conflicting and were only weakly comparable because of variations in research methods. Three studies showed a positive effect as a result of rehabilitation, 3 studies showed no effect, and the seventh showed a negative effect. Twenty years later (2003), Teasell et al[7] were unable to find substantially more depth or consistency in their review. They reviewed 272 randomized controlled trials (RCTs) but were unable to find even 2 RCTs confirming the efficacy of any particular treatment.[7] In 2002, Langhorne et al[8] observed that before the field of stroke rehabilitation can evolve into an evidence-based field of practice, the field must first establish a reliable evidence base. Ottenbacher and Jannell[9] noted that most RCTs in stroke rehabilitation are too small or scientifically inadequate to provide reliable guidance in establishing EBP.

Langhorne coordinated the Cochrane Stroke Unit Trialists' Collaboration (SUTC),[10] a meta-analysis of RCTs that compared dedicated stroke units with conventional care units in several European countries. The meta-analysis included 19 trials and concluded that stroke units have superior immediate and 1-year outcomes, in terms of function and survival. One would want to jump immediately into the data, to drill down and see what it was about the stroke units that produced the superior outcomes, but this level of data was not captured by any of the studies included. The best Langhorne could accomplish was to define stroke units as "geographically distinct wards with dedicated stroke teams, who provide coordinated multidisciplinary rehabilitation, programmes of education and training in stroke, and specialization of medical and nursing staff"[10]—and that is the extent of it.

Another problem of existing research on stroke rehabilitation is scientific rigor, with relatively few studies achieving what is commonly referred to as level 1 evidence. Moreover, the subject matter, selection criteria, measures used, and variables used in each study are sufficiently variable, making comparisons between studies difficult at best. The SUTC study supported the superior outcomes of stroke units[10]; Price and Pandyan's study[11] of poststroke shoulder pain supported the use of functional electric stimulation (FES). It cannot be known, however, whether the SUTC units used FES to improve their outcomes by reducing shoulder pain. This noncompatibility and lack of a comprehensive database compromises generalizability of results. Of course, not every study should be fully compatible with all others.

There has been substantial progress in the associated fields of neuroscience, radiology, medicine, and pharmacology to address the issues related to stroke management in recent years. Tissue plasminogen activator treatment protocols are gradually becoming the national standard of care for the initial presentation of an acute stroke at emergency departments.[12,13] Deep vein thrombosis prophylaxis is now routine and includes combinations of Doppler screening and the use of various antithrombotic drugs and compression devices.[14-16] Finding better methods to prevent initial and recurrent cerebrovascular accident remains an ongoing challenge for both the medical and research communities.[17-19]

In addition to published research, there are national databases that record various aspects of the inpatient rehabilitation stay. The Centers for Medicare and Medicaid Services (CMS), for example, requires that all IRFs acquire data on all their patients on admission and at discharge using the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI).[20] Moreover, accrediting agencies such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and Commission on Accreditation of Rehabilitation Facilities require that IRFs acquire outcome data on patients. JCAHO, for example, under the auspices of its ORYX initiative, requires that IRFs capture data on LOS, FIM score change, and discharge destination for each patient.[21] IRFs report these data mainly to 1 of 2 national data systems—to eRehabData.com of the American Medical Rehabilitation Providers Association, an industry trade association, or to the Uniform Data System for Medical Rehabilitation. The upside to these databases is that they bring greater uniformity to the acquisition of rehabilitation patient data and aid in making comparisons across facilities. The downside is that they lack the depth needed to effectively examine stroke rehabilitation practice in any detail—nor would we expect these databases to do so. These data sets are limited mainly to patient data captured at admission and discharge, and nearly everything that happens in between remains largely unknown—the proverbial black box of rehabilitation.

A few studies have begun the process of opening and examining rehabilitation's black box.[22,23] The excellent recent article by Bode et al[24] was a multicenter study looking at IRF-PAI data, billing data, and discharge data but was limited to a sample of 177 patients—indicating once again how difficult it has been to penetrate the black box.

The neuroplasticity thesis has also spawned new research that examines the efficacy of specific interventions. For example, there has been substantial research evaluating the applications of the constraint-induced movement theories of Taub et al,[25,26] and modified versions of the initial protocol appear promising.[27,28] These newer interventions, however, rarely are compared with existing interventions or other therapeutic approaches such as neurodevelopmental therapy (NDT) or proprioceptive neuromuscular facilitation (PNF). They are usually considered in isolation from the large bolus of other rehabilitation-related interventions. Research on mental and physical practice, applications of learning theory,[29] task-specific training,[30] and functional imaging have all contributed important concepts to the treatment of patients with stroke in the clinic today. They allow us, for example, to see activation patterns of the brain to help understand motor recovery.[31-35] We hope that the knowledge gained will lead to the develop-

ment of new training approaches. Other new technologies being tested are the use of virtual reality and robotics to aid in the recovery of lost function.[36-46] However, the best practices of existing therapeutic approaches have yet to be ferreted out.

The spring 2003 issue of *Topics in Stroke Rehabilitation* contained several detailed evidence-based reviews on numerous outcome and efficacy studies in stroke rehabilitation. Studies were rated based on the number and quality of RCTs. For example, Teasell et al[7] developed a list of clinical findings based on RCTs having strong level 1 evidence. These findings, however, are quite nonspecific. They suggest that stroke rehabilitation improves functional outcomes, but it is not known whether the physical therapists used NDT, PNF, body weight–supported (BWS) gait training, FES, or had the patient practice walking. Did the occupational therapists use FES, slings, shoulder taping, positioning, tone inhibitory techniques, shoulder injections, or some combination of these to achieve the greater intensity of therapy to improve functional outcome? Did the treatment of neglect include placing all items of interest on a patient's left side, or were red markings placed on the left side of all objects, or was there simply "maximal cueing"? Did patients with greater functional improvements receive serotonin-specific reuptake inhibitor antidepressants, stimulants, atypical antipsychotic medications, combinations of these, or none of these? To date, research on current practice has been able to tell us little more than that "rehab is good." Now it is time to drill down, to get to the nitty-gritty of inpatient stroke rehabilitation. What really happens, how often, and to what effect?

These kinds of questions are not answered easily using traditional clinical research methods such as RCTs unless one is prepared to apply an RCT to each of these variations of practice—a solution that is neither practical nor likely to occur given current limitations in rehabilitation research funding. Clearly, different methods must be found if we are to address the various combinations and permutations of practice, including methods that provide highly granular-level data and allow researchers to examine microprocesses such as the impact of shoulder-hand syndrome pain and its treatments on participation and progress in rehabilitation. The clinical practice improvement (CPI) method used in the PSROP addresses this need for more granular treatment data, as outlined in the next section.

The 1995 Agency for Health Care Policy and Research (AHCPR) Post-Stroke Rehabilitation Guideline on stroke rehabilitation provided a review[47] of the best research available at the time and supplemented that review with expert consensus recommendations in those instances where the literature did not provide level 1 evidence. The guideline panel found very few level 1 studies. Eight years later, in 2003, the Veterans Health Administration (VHA) issued its own stroke rehabilitation guideline[48] by significantly updating the work of the 1995 AHCPR guideline, taking into account the studies conducted in the intervening years. The PSROP database offers a rare opportunity to test the AHCPR and VHA guidelines by determining whether patients treated in keeping with the guidelines had better outcomes. A previous study of 288 stroke survivors at 11 VHA sites throughout the nation found that compliance with AHCPR guidelines was positively associated with outcomes.[49-51] Because this study was conducted within the VHA, it remains uncertain whether the findings generalize to women stroke survivors as well as men. The chief limitation in using the guidelines developed to date as a point of departure for future research is their lack of specificity, which mirrors the underlying literature's lack of specificity with regard to the exact nature and timing of rehabilitation therapies such as OT and PT, including their intensity, frequency, and duration—the very dimensions captured by the PSROP.

THE PSROP

The PSROP began initially as one of several projects under the auspices of the Rehabilitation Research and Training Center on Measuring Rehabilitation Outcomes hosted at Boston University's Sargent College and funded by the National Institute for Disability and Rehabilitation Research in 1999. The leadership team for the study was drawn from 2 organizations: the Institute for Clinical Outcomes Research in Salt Lake City, UT, and the National Rehabilitation Hospital's (NRH's) Center for Health and Disability Research in Washington, DC. As the scope of the PSROP increased, additional funding was provided by the NRH Neuroscience Center with a grant from the U.S. Army and Materiel Command. The National Blue Cross Blue Shield Association contributed to the acquisition of 6-month follow-up data from the NRH site. Various authors who contributed to this supplement did so under the auspices of their own funding sources in addition to those mentioned here.

The PSROP's Principal Research Question

The PSROP's main research question is an enduring one: what impact does each stroke rehabilitation activity or intervention, both individually and collectively, have on patient outcomes on discharge, controlling for patient differences including medical and functional status on admission? This rather global question can be partitioned into a series of subsidiary questions, several of which are addressed to one degree or another in the articles represented in this supplement. Answering these questions required the acquisition of detailed in-depth data on patient characteristics, processes of care, and outcomes and the creation of a large relational database that is described more fully in Gassaway et al.[52]

Critical to the success of the PSROP has been the steadfast participation of the study's 7 clinical sites in the design, data collection, and analysis phases of the project. The 7 sites participated vigorously and contributed far beyond the funding levels provided by the project. The 7 sites and their respective site directors are identified by Gassaway.[52] The participation of front-line clinicians was especially important to the study's attempts to characterize rehabilitation activities and to collect data documenting each stroke rehabilitation activity and intervention.

We distinguish between activity and intervention, a distinction underscored by the PSROP's clinical contributors. An activity, to borrow examples from PT, might include bed mobility, sitting, gait or walking, and community mobility. An intervention, to use PT again, may include strength exercises, aerobic or conditioning exercises, electric stimulation, parallel bars, BWS gait training, and family education, to cite only a few of the 57 interventions coded in the study. At the risk of some oversimplification, there are 2 broad levels at which individual therapies can be analyzed: the activity level and intervention level (ie, the therapy intervention used to facilitate each therapy activity). This supplement is limited largely to the therapy activity level and not to the intervention level. We seek first to determine how participation in individual activities—in terms of timing, duration, frequency, and intensity—shape outcome. In subsequent work we want to determine how interventions within select activities shape outcomes.

The PSROP's Methodologic Innovations in Rehabilitation Research

We devote an entire supplement to the PSROP because of its scope and depth but also because it breaks new ground in

rehabilitation research methods. One breakthrough has been the PSROP's approach to characterizing the black box of stroke rehabilitation. To do so, it was first necessary to develop a taxonomy of stroke rehabilitation activities and interventions. It was never the intent of the PSROP to develop a stroke rehabilitation activity or intervention taxonomy, but investigators and collaborating clinicians determined that they could not go further if they did not have a working taxonomy of activities and interventions that used a common vocabulary and uniform methods of documenting stroke rehabilitation activities and interventions. The de facto taxonomy that evolved from the study has been outlined previously by DeJong et al.[22] We do not present this taxonomy as a definitive one for stroke rehabilitation but believe that it serves as a working taxonomy that provides useful insights into how future and more formal stroke rehabilitation taxonomies might be developed.

The PSROP is a CPI-type of study that is essentially an observational cohort study with 3 added features. First, CPI studies systematically harness the collective wisdom of frontline practicing clinicians and use their insights in planning the study, defining the treatments to be evaluated, narrowing the hypotheses to be tested, developing the data collection instruments, and collecting and analyzing the data. Second, to control for patient differences, CPI studies capture the clinical complexity of each patient by using the Comprehensive Severity Index in addition to measuring functional status, a mainstay of rehabilitation studies. Third, CPI studies use detailed descriptors of rehabilitation processes made possible by the taxonomy of rehabilitation activities and interventions, as noted. Like many observational studies, CPI studies use multivariate analyses to identify the variables most associated with outcomes, but CPI's distinguishing features, particularly the detailed characterization of activities and interventions, allow researchers to unravel relations that might not otherwise become apparent. A full-fledged CPI study includes a fourth feature: it ascertains the predictive validity of the findings by evaluating the outcomes that result when study findings are introduced into practice as part of a larger practice improvement strategy, a feature that also gives this genre of study its name—clinical practice improvement. The PSROP did not include this fourth feature.

A CPI study's methodologic features also address some of the weaknesses found in RCTs. For more on the relative advantages of CPI and RCT studies, the reader is directed to a commentary by Horn et al.[53]

A central theme in clinical and health services research is the call for EBP, a call that is sometimes synonymous with a call for more RCTs in health care, including rehabilitation. Unfortunately, there may never be enough resources or time to address all the myriad forms of rehabilitation practice through randomized trials. There are no good shortcuts in rehabilitation research, but we do have to find a faster way of ascertaining what constitutes EBP in rehabilitation. Current methods for determining best practices are much too slow and too expensive. A strength of the CPI approach is its ability to uncover best practices more quickly than conventional methods, and such practices can later be vetted in validation studies or through controlled trials. A major challenge is knowing what therapeutic activities and interventions are truly ready for prime-time controlled studies. In the earnest quest for randomized studies, we risk wasting rehabilitation research resources on studies that may show no or minimal differences. Through the use of CPI-type studies, many promising therapeutic activities and interventions can he identified and unproductive activities and interventions weeded out in advance of such confirmatory studies.

The PSROP's Limitations

Every study has its limitations, and this study is no exception. First, the PSROP did not include data beyond discharge into the postrehabilitation period, except at 2 sites that had made independent efforts to follow up patients up to 6 months after their strokes. Hence, the PSROP can provide insight into the more immediate effects of stroke rehabilitation therapy but not into its long-term effects. The original level of funding simply did not permit the research team to probe beyond the rehabilitation episode, except in the 2 instances already noted.

Second, the study's documentations of nursing activities and interventions are not as strong as those for the mainline rehabilitation therapies. The study was conducted during a period of serious nurse shortages that, in some instances, compromised the completeuess of the nursing data, and thus these data are not reported in this supplement.

Third, as an observational cohort study, the PSROP focuses on the associations between various rehabilitation inputs and outcomes, not on causation of outcome. Nonetheless, as seen in subsequent articles, some findings and themes remain remarkably consisteut across different patient subsets and therapy activities.

Fourth, there are other real or perceived limitations—for example, potential selection bias and other classic study limitations—although 1 hallmark of this study has been its ability to control for patient differences through the use of a detailed severity-of-illness adjuster that probes well beyond similar tools. These and other limitations are addressed in the supplement's other articles.

Finally, the study's unit of analysis was very much at the patient level and did not address major differences such as organizational milieu and interdisciplinary team coherence—although team conferences were considered a rehabilitation activity or intervention. The long-standing work by Strasser et al[54] on rehabilitation team functioning has shown positive associations between various dimensions of teamness with patient outcomes. One could make the case that well-functioning teams result in better outcomes, because they organize care more efficiently at the patient level. They may also have an independent effect on outcomes because team culture may spill over onto therapist and patient mood and behaviors that affect the rigor of their participation. The PSROP did not capture this dimension of the rehabilitation experience.

Some Findings

The PSROP offers several insights into the stroke rehabilitation process as we know it today. We want to share an insight or 2 that transcend the individual articles represented in this supplement.

An important finding is the large practice variations between facilities represented in the study. For example, we find enormous variations in the use of medications such as antidepressants, with no clear clinical indications for the observed variations. We rarely think of medication as a distinct rehabilitation intervention in the same way we think of the 3 therapies most closely identified with rehabilitation—namely, OT, PT, and SLP. Moreover, the management of affective disorders can greatly affect a patient's ability to participate in these therapies. There is much room to identify best, or at least better, practice in this area.

The PSROP also examines the relative distribution of therapy activities within and between the 3 main rehabilitation therapies. PSROP investigators are struck, for example, by how little attention is given to community mobility and integration activities relative to other therapy activities. Future studies will

need to determine how the neglect of these areas affects longer-term outcomes. Such studies are needed to inform providers, health plans, and other payers about the relative merits of these activities in fostering greater community independence and mobility after discharge.

One of the more compelling insights to emerge from the PSROP and the articles presented here is that earlier and more aggressive therapy is better, controlling for patient differences. In other words, starting therapy earlier is better than later, and moving patients on to higher-order and more difficult activities more quickly has a way of resolving some of the lower-order activities that rehabilitation providers sometimes focus on as necessary steps to more advanced activities. The earlier-is-better observation confirms many previous studies. The more-aggressive-is-better finding presents new opportunities to improve practice and presents new hypotheses for research. The case for the earlier-and-more-aggressive finding is also evident in some of the differential findings between the United States and New Zealand facilities. Compared with New Zealand facilities, U.S. facilities provide a more aggressive shorter-term program of rehabilitation with better outcomes, despite a more challenging case mix.

SCOPE AND ORGANIZATION OF THE SUPPLEMENT

This supplement consists of 11 articles and 1 commentary, plus 2 commentaries by third parties. The second piece in this series is a commentary that raises fundamental epistemologic issues in rehabilitation research and identifies the methodologic genre of research from which the PSROP springs. In short, it provides the methodologic context that also enables the reader to understand better the contributions and limitations of the PSROP.

The third article[52] serves as the common methods piece and baseline findings for the articles that follow. We chose to provide a separate baseline article describing the study's methods and the study group's principal characteristics because of the PSROP's nontraditional approach and because the baseline article reduces the need for each subsequent article to repeat all the same background material with respect to study design and study group characteristics. Instead, each subsequent article's methods section summarizes the study's overall methods and focuses on those methods that are more specific to the topic of the article, especially if subsets of the study group were used and not the entire study group. We encourage readers of subsequent articles to have a basic acquaintance with this baseline article to more fully interpret the findings of individual articles that follow and to understand the limitations of the study. We also encourage readers to become acquainted with an earlier article[22] published by the study team on stroke rehabilitation intervention taxonomies, as noted earlier.

A long-standing issue in rehabilitation is the timing of rehabilitation—timing from onset of the stroke and timing from acute hospital care to rehabilitation. The conventional wisdom has been that early rehabilitation results in better outcomes and that undue delays from acute care to rehabilitation result in further deconditioning and atrophy that limit participation in therapy or require a more prolonged rehabilitation process. The supplement's fourth article examines this question and confirms much of the conventional wisdom on this topic.

The supplement's fifth, sixth, and seventh articles examine and characterize the content of inpatient rehabilitation's 3 main therapies—PT, OT, and SLP. Previous studies have been able to quantify the hours or minutes of therapy received over the course of an inpatient rehabilitation stay, but they provide little insight into the actual content of the 3 therapies with respect to specific activities and interventions and how much of each therapy activity or intervention was associated with higher levels of function and independence. The authors examine how participation in select therapy activities relates to progress in specific functional activities (eg, gait training, walking).

The authors of the 3 therapy articles do not attempt to show how participation in select activities relates to overall functional status at discharge and discharge disposition. This discussion is reserved for the supplement's 11th article, in which we bring all the independent variables together in explaining the study's observed outcomes. One of the lessons learned is that there is overlap of activities across the 3 therapies and that looking at these activities within the confines of the individual therapies in isolation from the other therapies provides an incomplete picture of the therapeutic encounter. The take-home message from this experience is that we cannot examine rehabilitation practice and therapy merely through the lens of individual therapy professions but need to look across professional domains to understand more fully how individual therapy activities and interventions relate to functional outcomes.

In addition to rehabilitation's 3 core therapies, there are many other rehabilitation activities and interventions that the PSROP examined. We can report on only a few of these in this supplement. The supplement's eighth article examines the use of neurotropic drug therapy. Many patients with stroke experience poststroke depression or other affective disorders that may slow their recovery, limit their participation in therapy, and diminish their outcomes. The authors believe that drug therapy is an understudied area of stroke rehabilitation that is ripe for more significant advances in rehabilitation practice and outcome.

Similar observations could be made about the role of nutrition in stroke rehabilitation outlined in the supplement's ninth article. Many patients with stroke come to rehabilitation malnourished or inadequately hydrated either because of long-standing behaviors or because their new impairment may limit their ability to consume a more balanced diet. Nutrition is not commonly thought of as a rehabilitation intervention, but malnourished patients may lack the energy and mental focus needed to participate more effectively in rehabilitation therapy. In this area as well, we have observed considerable variation in practice and believe that a better understanding of the role of nutrition and malnutrition may help accelerate the rehabilitation process.

Midway through the PSROP, CMS implemented the long-awaited prospective payment system (PPS) for IRFs. The IRF-PPS presents important financial incentives that are likely to reshape provider behavior and rehabilitation practice. We believe that we cannot ignore this development and, coming midway through the PSROP data collection process in 2002, we have a singular opportunity to examine how the IRF-PPS may have altered the mix of stroke rehabilitation patients, the extent of therapy rendered, and the LOS. The supplement's 10th article provides a before-and-after–PPS view of stroke rehabilitation in 3 of the 6 U.S. facilities that had significant numbers in both the pre- and post-PPS periods. This article, however, did not find striking short-term changes in stroke rehabilitation practice, as had been expected.

The supplement's 11th article considers all the findings of the previous articles to help identify likely predictors of rehabilitation outcome in terms of functional status on discharge and discharge disposition. We chose not to examine these outcomes in previous articles except tangentially, in part because we believe that all patient and process variables cannot be evaluated independently of one another. Moreover, as noted earlier, the overlap in therapies across professional domains

requires an integrated analysis that simply cannot be achieved by looking at the impact of therapies in isolation from one another.

The PSROP's seventh site, the Wellington and Kenepuru hospitals in Wellington, NZ, provides an international dimension to stroke rehabilitation practice. The supplement's 12th article examines how stroke rehabilitation practice in New Zealand is both similar to, and different from, stroke rehabilitation in the United States as represented by the 6 U.S. sites. We added New Zealand to the original U.S. cohort in the interest of locating additional variation in practice that might not be available in the United States. (The original PSROP study design included SNFs as well as IRFs. In 2000 and 2001, when the PSROP got underway, the SNF industry was experiencing considerable turmoil in the wake of changes resulting from the Balanced Budget Act of 1997, and surviving SNFs were difficult to recruit.) Unlike RCTs, which require very rigid adherence to practice protocols, CPI studies like the PSROP thrive on practice variation to help differentiate intervention effects that might otherwise be more difficult to identify when there are fewer practice differences.

Although the New Zealand site is the only non-U.S. site in the study, the PSROP is very similar to a 4-country, 5-site study on stroke rehabilitation currently underway in Europe, known as the Collaborative Evaluation of Rehabilitation in Stroke across Europe (CERISE). Sponsored by the European Commission, the study is being led by a team of investigators in Belgium at the Free University of Brussels and the Catholic University at Leuven. CERISE and PSROP investigators currently are examining ways to merge their 2 databases to provide a richer cross-national understanding of stroke rehabilitation practice and outcomes and to achieve a level of understanding that cannot be achieved by the 2 databases independently. Moreover, because the CERISE study ascertained 6-month outcomes, merging these 2 data sets will enable researchers to make more effective use of the 6-month outcome data obtained from 2 of the PSROP sites—one in the United States and the other in New Zealand.

CONCLUSIONS

Given the depth and scope of the PSROP database, there is a great deal more to be explored than is represented in this supplement. The research and findings presented here offer insights as to how we can understand practice variation and find best practices in stroke rehabilitation. The search for EBP begins with a better understanding of current practice. All too often, the quest for innovation ignores the gems that already exist in current practice and within the collective wisdom of rehabilitation practitioners. The PSROP offers 1 way in which these gems can be identified and disseminated into mainstream stroke rehabilitation practice.

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COMMENTARY

Another Look at Observational Studies in Rehabilitation Research: Going Beyond the Holy Grail of the Randomized Controlled Trial

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ABSTRACT. Horn SD, DeJong G, Ryser DK, Veazie PJ, Teraoka J. Another look at observational studies in rehabilitation research: going beyond the holy grail of the randomized controlled trial. Arch Phys Med Rehabil 2005;86(12 Suppl 2): S8-15.

This commentary compares randomized controlled trials (RCTs) and clinical practice improvement (CPI) approaches to study design, evaluates their relative advantages and disadvantages, and discusses their implications for rehabilitation research and evidence-based practice. Many argue that observational cohort studies are not sufficient as scientific evidence for practice change. We challenge this assertion by introducing the concept of a CPI study: a comprehensive observational paradigm structured to decrease biases generally associated with observational research. One strength of CPI studies is their attention to defining and characterizing the "black box" of clinical practice. CPI studies require demanding data collection, but by using bivariate and multivariate associations among patient characteristics, process steps, and outcomes, they can uncover best practices more quickly while achieving many of the presumed advantages of RCTs.

Key Words: Cerebrovascular accident; Clinical practice variations; Rehabilitation; Treatment outcomes.

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A RECURRING CRITICISM in medical rehabilitation is the lack of adequate high-level research evidence with which to establish evidence-based practice. This criticism is not unique to rehabilitation and is echoed throughout the health care system. Tunis et al write,

> The current clinical research enterprise in the U.S. is not consistently producing an adequate supply of information to meet the needs of clinical and health policy decision makers . . . [due to] a systematic problem in the production of clinical research. . . . A consistent finding of [systematic literature] reviews is that the quality of evidence available to answer the critical questions identified by experts is suboptimal. . . . These gaps in evidence undermine efforts to improve the scientific basis of health care decisions. . . . [such that] clinical practice guidelines may not be able to develop clear, specific recommendations. [Typical] observational and other non-experimental methods may not provide sufficiently robust information regarding the comparative effectiveness of alternative clinical interventions, primarily because of their high susceptibility to selection bias and confounding variables.[1(p1625-6)]

Tunis calls for new research methods to meet these gaps. Berguer[2] discusses problems with the evidence in evidence-based medicine (EBM). The main tools of EBM are randomized trials and meta-analysis, but Berguer believes that these methods are unlikely to lead to the discovery of new and best treatments for specific types of patients. "[Rigorous] observational and inductive clinical intelligence should be stimulated and published because a therapy needs to be invented before it is proven effective. Biomathematicians need to improve nonrandomized methodology as they did for randomized studies."[2(p265)] To paraphrase Berguer, randomized controlled trials (RCTs) are important to the confirmation of new and/or current interventions and practices, not to the discovery of more effective and efficient interventions and practices.

There are additional calls for new approaches to EBM and performance in quality and costs of the health care system. Porter and Teisberg write, "The U.S. health care system has registered unsatisfactory performance in both costs and quality over many years."[3(p64)] They observe that medical services are restricted or rationed, many patients receive poor care, and high rates of preventable medical errors persist. There are wide and inexplicable differences in costs and quality among providers and across geographic areas. In well-functioning competitive markets, Porter and Teisberg argue, such outcomes would be inconceivable; in health care these results are intolerable. Competition in health care is operating at the wrong level: payers, health plans, providers, physicians, and others in the system wrangle over the wrong things. "System participants divide value instead of increasing it."[3(p65)] This form of zero-sum competition must be replaced by competition at the level of preventing, diagnosing, and treating individual conditions and diseases and determining the best treatments for specific types of patients. Encouraging competition at the level of treatments for specific diseases or co-occurring conditions and types of patients will speed the development of the right kind of information and improve value (quality of health outcomes per dollar expended). Value should be measured and improved at the disease and treatment level.[3]

Tunis's call for developing the next phase in the evolution of clinical trials is, namely, pragmatic or practical clinical trials

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(PCTs), for which the hypothesis and study design are developed specifically to answer the questions faced by decision makers in practice or as payers. "Characteristic features of PCTs are (1) select clinically relevant alternative interventions to compare, (2) include a diverse population of study participants, (3) recruit participants from heterogeneous practice settings, and (4) collect data on a broad range of health outcomes."[1(p1624)] "PCTs address practical questions about the risks, benefits, and costs of an intervention as they would occur in routine clinical practice"[1(p1626)] and address questions such as the following: Does the treatment work in the real world of everyday practice? For whom does the intervention work best? The PCT approach contrasts with explanatory clinical trials or efficacy studies (RCTs), which are concerned with questions such as the following: Does the investigational treatment cause an effect? How and why does the intervention work? Explanatory trials are designed to maximize the chance that some effect of a new or existing treatment will be revealed by the study. They are a form of confirmatory analysis where relations have been vetted already in previous research.

This commentary presents the clinical practice improvement (CPI) research method as a variant of the PCT called for by Tunis. As a clinical research method, CPI embraces all 4 elements of PCTs outlined above and, thus, is one way in which the PCT concept can be operationalized effectively.[4] The purpose of this commentary is to juxtapose RCT and CPI research methods by evaluating their relative strengths and weaknesses. We argue that PCT methods such as CPI can liberate us from the straightjacket that has constrained rehabilitation's ability to discover and establish standards for best practice.

RCTs: FEATURES AND CHALLENGES

The intellectual origins of RCTs come from agriculture. In agricultural hothouses, the environment can be reasonably controlled and various interventions tested. The RCT represents a research paradigm that had its origins in a simpler time when we did not have powerful multivariate statistical tools, and even when we had them, we lacked the computational power that readily accessible computer-based statistical packages have brought us over the last 30 years. As a research model, the RCT allowed one to make relatively simple computations using fairly small sample sizes; it was well suited to the computational constraints of an earlier era. RCTs do not harness the full power of multivariate statistics, in which many variables can be considered simultaneously and covariates can be identified and neutralized to evaluate intervention effects.

A hallmark of an RCT is the random assignment of study participants into a treatment arm and a control arm to neutralize participant differences that might otherwise affect the outcome. By neutralizing participant differences through randomization, RCTs help isolate the effect of the treatment under review. Nonrandomized comparison groups present the risk that some nontreatment effects remain unaccounted for and thus compromise one's ability to have full confidence that the outcomes are truly a consequence of the treatment or intervention under study.

When designed and conducted properly, RCTs are considered the criterion standard for establishing causality in scientific research. Clinical and health services research communities have come to accept hierarchies of evidence where RCTs are considered the highest level of evidence and anything less than RCT-level evidence is considered somewhat suspect. Using RCTs in rehabilitation presents several major challenges that are not easily overcome. We mention a few of them here and later discuss how a CPI approach is not bound by many of the same constraints.

Standardization and Artificiality

RCTs require that one use standardized treatment protocols and that one hold all other variables constant to isolate the effects of the intervention and to reduce noise in the data. One result is that the intervention setting can become artificial and may not reflect what would otherwise transpire under less-controlled circumstances in a real-world clinical environment. Standardized treatment protocols require extensive quality control to decrease error rates about the treatment. Treatment purity is difficult to maintain over time, across centers, and across clinicians; if compromised, an intention-to-treat analysis—which keeps everyone in the study and in their assigned groups even if the treatment protocol or control is not followed as prescribed—may be the best remaining analysis option. Unfortunately, intention-to-treat analyses no longer reflect efficacy.

Selection Criteria, Patient Recruitment, and Generalizability

Selection criteria for participation in a study are often quite restrictive to reduce variation stemming from differences among study participants. Restrictive selection criteria limit the generalizability of a study's findings (external validity) to the types of people represented in the study. The study's findings may not apply to the types of people excluded from the study. For example, many studies exclude people with comorbidities, although significant comorbidities are common in many rehabilitation populations and may affect or alter outcomes. Clinicians may be prone to dismiss RCT findings, because they deem their patients to be quite different from those seen in a clinical trial. Restrictive selection criteria can also result in studies with very small numbers, drawn from a much larger pool of otherwise eligible participants. Typically, only a small percentage of patients—usually 10% to 15%—are eligible for a trial. Enormous resources must then be expended to recruit large pools of potential participants to locate people who meet the selection criteria and thus achieve the sample sizes needed to power the analyses.

Blinding

RCTs assume some degree of blinding. Ideally, all 3 actors—the study participant, the clinician, and the researcher or observer—are unaware as to whether the participant is in the treatment or control arm. Double blinding means that 2 of the 3 are blinded—both the participant and 1 of the other 2 actors—lest their knowledge about participant assignment affect their level of effort, their outlook, and the participant's willingness to continue with the nontreatment arm of the study. Rehabilitation interventions, including sham interventions, are not easily disguised and, in many cases, are impossible to disguise.

RCTs present other challenges, including ethical challenges to randomization and lengthy planning and approval processes that can sabotage even the best-designed studies. Most formidable is cost: an RCT can be very expensive, even prohibitively expensive, because it may require an elaborate protocol to screen patients, coordinate care, and collect data. For example, the Medical Outcomes Study and the Health Insurance Experiment conducted by Rand in the 1980s cost sponsor organizations more than $35 million and over $60 million in 2005 dollars. Other large RCTs of practice effects cost about the same.

All of this leaves rehabilitation in a real bind. On one hand, rehabilitation practice needs the validation that sound scientific evidence can provide. On the other hand, its highly customized multifactorial approach does not lend itself well to RCTs, which require a more limited set of interventions and selection criteria that can make participant recruitment difficult and expensive and make study findings less generalizable. We quickly could exhaust a good portion of the world's entire biomedical research budget in a given year to study all the rehabilitation interventions and combinations of interventions used around the world. Over the years, many variants of the RCT have evolved to address 1 or more of the challenges identified but cannot overcome limitations that are inherent in an RCT.

OBSERVATIONAL DATA AND CAUSAL INFERENCES

It is generally accepted that a decision is unwarranted if the supporting evidence is based on accidental associations. Confidence in an action depends on confidence that the supporting evidence implies a causal connection. As mentioned above, randomization underlying the RCT provides a relatively high degree of confidence in this regard, but the resulting evidence can be costly to obtain, not germane to the relevant clinical context, and easily compromised by small deviations from the design. An alternative is to use data with a naturalistic genesis representing the population and circumstances of interest. In such data, however, subjects are not randomized into the various treatment groups; consequently, analyses often cannot discern whether differences in outcomes are due to different treatments or to other differences between subject groups.

This problem has generated considerable effort to create methods that identify treatment effects using observational data. Since the last quarter of the twentieth century, a large literature has developed on causal inferences and observational data.[5-11] Methods have been created that allow for unbiased estimates of treatment effects by controlling for unmeasured confounders.[8,11] Unfortunately, these methods cannot identify all treatment effects of interest and are often sensitive to assumptions that are not testable. Also, they require considerable knowledge in statistics to understand and adjust sufficiently for nuisances, making them less useful to researchers and less understandable to decision-makers who do not have the requisite statistical background.

Alternatively, methods that sidestep the issue of unobserved confounding have been developed as well. Specifically, the method of instrumental variables allows for estimation of treatment effects in the presence of otherwise unobserved confounding.[12] However, the treatment effect is instrument-specific and may not be of interest. In addition, it can be difficult to identify and measure the required variables, and—similar to the preceding methods—the necessary assumptions are not testable. As another alternative, the observed data can be analyzed as if there are no unmeasured confounders and then subjected to a sensitivity analysis of potential confounding.[7] To be useful, however, this approach requires assumptions regarding the unknown confounding, and little is gained if results are determined to be sensitive to assumptions.

With enough data, if all factors influencing the distribution of both the interventions of interest and the outcomes of interest are measured and controlled for in analysis, then treatment effects can be identified from observational data without the need for sophisticated statistical models and untestable assumptions. Unfortunately, when confounding factors are not controlled statistically, the treatment effect may not be distinguishable from spurious correlations. It has been shown that under some circumstances controlling for only a subset of confounders can generate greater bias than controlling for none.[13-15] Heckman and Navarro-Lozano[13] provide a formal development of the point. Intuition suggests that if a set of factors have counterbalancing correlations with the outcomes and treatments (ie, some positive and some negative), then controlling for a select few can throw off the balance and generate greater bias.

Because in real-world settings it is not likely that all confounders can be identified and measured, a researcher is faced with 3 options: (1) pursue a costly RCT that may not address the clinical context of interest, (2) embark on statistically sophisticated methods that trade one set of untestable assumptions (ie, the identification of all confounders) for another set of untestable assumptions (the necessary distributional or correlation assumptions underlying selection and instrumental variable models), or (3) report an analysis that does not account for confounding, mention the deficit as a limitation, and let the user beware.

However, if the goal is to produce useful information and reduce uncertainty for decision-makers, the situation may not be so constrained. We suggest a paradigm shift toward the pragmatic. As stated at the beginning of this section, it is generally accepted that the decision to pursue a course of action is unwarranted if based on evidence of an accidental association; consequently, structuring research to minimize the potential for accidental association will improve its usefulness.

Rather than focus on meeting conditions for statistically unbiased causal effect estimates, we propose designing observational studies that focus on minimizing the plausibility of alternative explanations while estimating the complex associations between treatments and outcomes within a specific context of care. The identified associations are not equated with causal parameters but nonetheless inform such judgments to the extent that the design minimizes alternative explanations. This is a process-oriented approach: the goal is to structure the design carefully to capture the salient information bearing on the research question. The proposed design trades uncertainty regarding generalizability in the case of the RCT, or uncertainty in necessary assumptions underlying the statistical methods mentioned above, for uncertainty regarding the potential for alternative explanations while explicitly minimizing the plausibility of such explanations. Also, the proposed CPI method is available for use by most researchers with access to the standard computational power of today's personal computers and a knowledge of basic multiple regression techniques.

CPI: FEATURES AND CHALLENGES

CPI harnesses the complexity presented by patient and treatment differences, offering a naturalistic view of treatment by examining what actually happens in the care process.[4] It does not alter the treatment regimen to evaluate the efficacy of a particular intervention as one does in an RCT. The CPI approach offers the advantage of large numbers of patients—numbers that often cannot be attained in an RCT constrained by stringent selection criteria.

CPI is an observational study design whose measurement encompasses a comprehensive view of the care management process: (1) key patient characteristics, (2) all treatment and care processes, and (3) outcomes. All 3 classes of data are considered simultaneously (fig 1). This comprehensive measurement framework provides a basis for meaningful analyses of significant associations between process and outcome, controlling for patient differences.

CPI designs include detailed measures of patient factors (physiologic severity of illness and psychosocial abnormalities

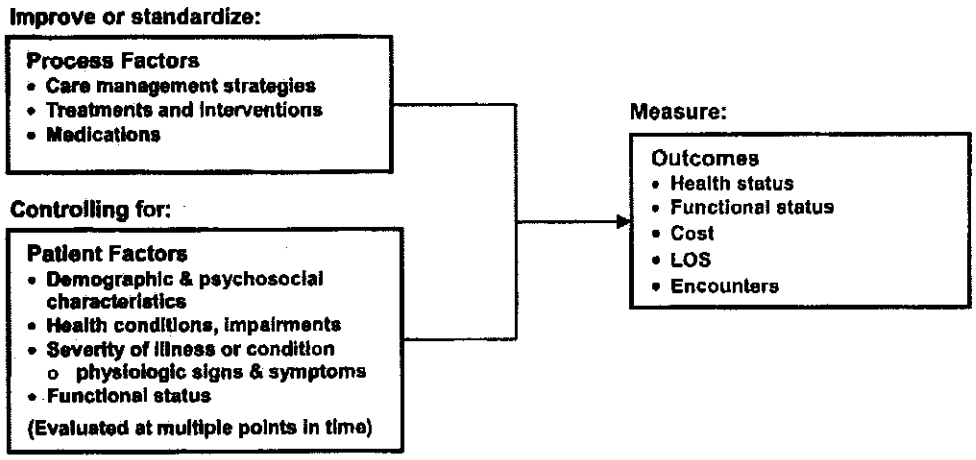

Fig 1. Three essential components for a CPI study. Abbreviation: LOS, length of stay.

presented at each visit or each admission), care process factors (eg, medications, treatments, interventions), and outcome factors. It presents the resulting associations to clinicians, so they can evaluate objectively the effects of the treatments they give to similar patients. Without all 3 types of data (eg, if one has only process and outcome data, but not detailed patient data), clinicians cannot tell if the outcomes achieved are due to the process steps or to differences in patients' illness severity levels.

Patient Factors

Patient factors are the key characteristics of the study population: demographic characteristics, specific indications for treatment, severity of illness, initial functional status, psychosocial factors, and others. A CPI design addresses a central feature in RCT design—namely, the need for randomization to neutralize the effect of patient differences. Randomization is used when patient differences cannot be taken into account adequately. On the other hand, CPI studies incorporate detailed information about patients and their needs and account for these differences through statistical analyses to control for patient differences. Detailed patient profile data include condition-specific physiologic data, such as those contained in the Comprehensive Severity Index (CSI).[4,16-21] The CSI is described in detail in the article[22] outlining the study's methods and is a unique severity-of-illness measure used in CPI studies.

Care Process Factors

A process of care is a sequence of linked, usually sequential, steps designed to cause a set of desired outcomes to occur. The goal is to find a measurable factor that describes each major process step. Examples include which drugs are dispensed, what dose is used, and what rehabilitation therapies are performed and for how long. A data collection instrument records the process steps in detail, including timing and dates. Thus, CPI studies require that clinicians and researchers characterize fully and accurately the actual interventions used. The level of detail about processes and interventions contained in CPI studies is unique.

Outcome Factors

Processes of care are designed to achieve specific outcomes. Among the outcomes commonly assessed are condition-specific complications, condition-specific long-term medical outcomes (based on clinician assessment or patient self-report), patient functional status, patient participation in society, patient satisfaction, and cost. Outcome factors may be thought of as analogs to the assessment endpoints in an RCT.

To capture all of these factors, CPI studies entail the creation of a large study database that includes all the patient, process, and outcome variables of interest. Multivariate statistical methods are then used to compare alternative treatments while controlling for other variables that may be driving observed differences between treatments and outcomes. These statistical methods allow the researcher to examine relations far more complex than those using only 1 explanatory or treatment variable at a time. The coefficients of the significant independent variables in regression equations identify key process steps that, when controlling for patient factors, are associated with better outcomes.

The CPI focuses on application—that is, on actionable findings that can be implemented to improve the process of care and treatment outcomes. The focus on implementation also governs who is involved in the study design, what data are collected, what questions are answered during analyses, and who designs the protocols or improvements in routine practice. Thus, CPI studies place a premium on the participation of clinicians in the study design, study execution, analyses of data, and implementation of study findings. Those actually providing the care are involved in all phases of the project, and their involvement also facilitates the buy-in needed to implement the findings and the care improvement processes.

RCT AND CPI STUDIES COMPARED

Table 1 compares RCT and CPI studies across several dimensions. We argue that CPI-like observational studies can help overcome some of the limitations that are inherent in RCTs. The conventional wisdom, however, is that RCT studies provide superior evidence relative to observational studies, yet there is growing empirical evidence that supports the use of well-designed observational studies akin to CPI studies relative to RCTs to discover what works best in medicine. Two studies[23,24] found that treatment effects from observational studies and RCTs were remarkably similar. Both studies concluded that they found little evidence that estimates of treatment effects in well-designed observational studies were either consistently larger than or qualitatively different from those obtained in RCTs. A third article found the same thing: comparing results on 45 topics with binary outcomes there was "very good correlation ... between summary odds ratios of randomized and non-randomized studies

$r=0.75$, $P<.001$ for all studies,

$r=0.83$, $P<.001$ for prospective studies."[25(p821)]

Table 1: RCT and CPI Studies Compared

Variables	RCT	CPI
Patient variables	Patient eligibility and stratification factors	Patient eligibility and stratification factors
	Eliminate patients who could bias results: comorbidities, more serious disease, etc	Use severity of illness to measure comorbidities and disease severity
	About 10%–15% of patients qualify	All patients qualify by measuring patient differences; none excluded
Process variables	Treatment protocol	Measure or record all treatments and interventions
	Specify explicitly every important element of the process of care for both treatment and control arms	Abstract information from charts based on existing practice
	Informed consent	Informed consent often not needed*
Outcome variables	Powered for primary outcome	Many outcomes assessed
	Change based on evidence	Improvement based on evidence
Measurements/ documentation	Limited number of patient variables, treatments, outcomes measured	Comprehensive holistic framework
	Variables specified precisely for all patient, treatment, and outcome measures	Variables specified precisely for all patient, treatment, and outcome measures
Database	Limited to the variables needed	Comprehensive and detailed
Result	Efficacy	Effectiveness
	Assigned causality	Association and assumed causality
Hypotheses	Typically 1 hypothesis	Typically many hypotheses
	Clearly defined at the start	Many and broad at the start
	Narrow and focused	Refined and new hypotheses generated by analytic findings
Local knowledge	Not dependent on local knowledge	Depends on local knowledge; entails participation by practicing clinicians
Confounders	Assumed not relevant to study or outcome	Affect outcomes and are relevant to include

*Informed consent may not be required if there is no experimental intervention and if there are no data collected beyond what is ascertained from medical records and from reports prepared by clinician in the course of usual care.

These studies concluded that well-designed observational studies do not systematically overestimate the magnitude of the effects of treatment as compared with those in RCTs on the same topic. In addition, "the popular belief that only RCTs produce trustworthy results and that all observational studies are misleading does a disservice to patient care, clinical investigation, and the education of health care professionals."[24(p1892)]

CPI has the ability to identify important associations in many diagnostic groups. Table 2 gives examples of CPI studies and selected treatments that were associated with better patient outcomes, their positive impacts on patients, and their positive impacts on health care systems (eg, reduced length of stay and/or costs).[26-37]

DISCUSSION

A key advantage of a CPI study is the naturalistic view of medical treatment that is provided by retrospective data recorded routinely by medical providers. This view is critical to determine implications of treatment alternatives. In everyday practice, patients are assigned to different treatments based on the provider's medical judgment, patient compliance is not artificially influenced, and monitoring of results is based on the provider's need for information about how a patient is doing. All these factors can affect the effectiveness of medical treatment. CPI analyses help the team evaluate current practices and use the results to develop evidence-based improvements. Changes to the process of care rest on clinical data rather than on clinical opinion.

This approach directly contrasts the approach of traditional RCTs. Because their participants are screened, selected, and subjected to scrutiny and intervention control beyond that occurring in everyday treatment, RCTs sometimes report results that are not broadly applicable in everyday medical treatment. For example, a recent study described a little-used 40-year-old drug, spironolactone, which was shown in a landmark clinical trial in 1999 to significantly reduce death and hospitalization for patients with congestive heart failure.[38] There was a 4-fold jump over 18 months in prescriptions for the generic drug. That surge in use was accompanied by a tripling of hospital admissions and of deaths resulting from dangerous elevations of potassium. Many patients given the medicine likely would have been excluded from participating in the original clinical trial. The researchers noted that the new findings offer a provocative look at the difference between clinical trials and real-world medicine—and the potential dangers of applying trial results too widely. Patients in clinical studies typically are selected carefully to maximize the chance of showing a benefit and minimize side effects. Thus, trial patients represent only a subset of the types of patients doctors treat in their offices. Patients given the medicine in the aftermath of the 1999 study were on average 13 years older than participants in the original trial and were more likely to have diabetes. Also, the average dose in actual practice was 30mg, whereas 25mg was used in the study.[38] CPI studies can provide evidence to determine those medications and interventions that work best for specific types of patients in real-world practice.

Another key advantage of CPI study methods is cost. Using existing data from medical records and computerized databases is generally much less costly than implementing a prospective RCT. Using retrospective data allows for a much larger number

Table 2: Examples of CPI Studies, Selected Findings, and Their Effects

CPI Project	Selected Significant Findings	Associations	Implications
Abdominal surgery[32]	Early feeding (start within 48h after surgery) Sufficient feeding (>60% of protein and calorie needs)	Shorter LOS Lower hospital cost	Even though they had higher average severity of illness, patients fed early and sufficiently had between 1.4 and 2.9 days shorter average LOS and between $1940 and $5281 lower average cost per case than patients fed either not early and/or not sufficiently
Abdominal surgery[29]	Use of PCA pump	Higher rate of postoperative surgical wound infection	10.7% infections for PCA users vs 4.0% for non-PCA users
National Pressure Ulcer Long-Term Care Study[31]	Disposable briefs Supplement use Combination medications	Fewer pressure ulcers	Less suffering and lower cost to treat in nursing homes
Formulary limitations in the elderly[35]	Greater formulary limitations	Higher health care resource utilization—more doctor office visits, more ED visits, and more hospitalizations per year	Common cost-containment strategies are associated with higher health care resource utilization
Asthma drugs[36]	Use of newer asthma drugs	Lower overall drug costs and fewer PCP visits per year	Common cost-containment strategies are associated with higher health care resource utilization
Diabetes study[37]	Self-monitoring of blood glucose along with consistent provider discussion	Better serum glucose control and fewer hospitalizations	Monitoring alone is not sufficient; discussion of results with providers is essential
Infants hospitalized with RSV[30]	33–35wk gestational age infants hospitalized with RSV	Higher intubation and longer ICU and hospital LOS	Consider prophylaxis for 33–35wk gestational age infants

Abbreviations: ED, emergency department; ICU, intensive care unit; LOS, length of stay; PCA, patient-controlled analgesia; PCP, primary care provider; RSV, respiratory syncytial virus.

of observations that can be available for analysis and for further hypothesis generation and refinement.

Observational studies do not scientifically prove the causality of any underlying relations, but they can point to hypotheses that can be evaluated clinically. There are 3 ways to ascertain causality from CPI studies: (1) no added confounders cause the significant association to disappear, (2) a change in outcome follows a change in treatment as predicted by the CPI model,[4] and (3) repeated studies on the same topic yield the same findings. In short, CPI studies have shown predictive validity because observations show that outcomes change as predicted when practices are changed to those associated with better outcomes in the CPI analyses.

An RCT cannot always be conducted in rehabilitation medicine when sufficient evidence of treatment efficacy does not exist to justify one, projected sample sizes are small, or the question cannot be studied with an RCT (eg, what is the role of psychologic disturbances in outcomes). However, safeguards and protections built around RCTs (other than randomization) can be used in research methodologies such as observational studies, thereby increasing the level of evidence provided by studies using research designs other than RCTs. CPI does this by developing a comprehensive database of patient, treatment, and outcomes variables.

Instead of being viewed as competitive or mutually exclusive, RCTs and CPI should be considered complementary. Practice effects of RCTs can be tested in CPI studies, and CPI can be a progenitor of new RCTs.

Today, data needed to conduct a CPI study typically are abstracted by hand from existing paper medical records or documented prospectively on standardized forms. In the future, hospitals will use computerized clinical information systems (CISs). Then, rather than relying on labor-intensive manual data abstraction, needed patient, process, and outcome data can be found electronically in hospitals' CISs. The efficiency and logistics of this new data acquisition modality will make it easier and less costly to conduct iterative CPI studies to determine best practices. Also, the resulting research-based protocols can be programmed into a hospital's CIS to alert clinicians to the most appropriate protocols or interventions needed to address specific combinations of patient signs and symptoms. This should result in more consistent implementation of clinical practice guidelines and the protocols suggested by such guidelines.

CPI studies constitute a rigorous form of quasi-experimental research. Although they are weaker than RCTs on internal validity, they are stronger on external validity. CPI studies better represent actual conditions of practice, and they usually cost less and take less time. Because they do not insist on homogeneous patient populations, they allow the inclusion of patients with comorbidities or complications. To avoid confounding the link between the interventions and outcomes, they measure relevant

patient characteristics using severity assessment tools and statistically adjust for differences in patients. Further, they accommodate departures from rigid treatment protocols by carefully monitoring and measuring actual treatments; they then use these data in statistical analysis. Because this approach does not disqualify large numbers of patients, it facilitates the generation of the number of cases needed for comparisons. Using multiple regression and other statistical techniques, researchers test process steps that are associated with the quality and cost outcomes sought for different kinds of patients.

Although CPI studies tend to focus on short-term outcomes, these outcomes include effects that are noticeable and holistically important to patients rather than only those that are physiologically measurable through laboratory or other tests. CPI studies are designed to be replicated easily so they can be undertaken at multiple sites.

In a commentary on alternatives to RCTs for traumatic brain injury rehabilitation, Whyte states, "It appears nearly impossible to successfully apply observational designs when the factors leading to the applications of different treatments are strongly related to the patient's perceived prognosis."[39(p1320)] CPI adjusts for this by using condition-specific, physiologic-based measures of severity such as the CSI and other control variables.

CONCLUSIONS

The most appropriate design for a specific study depends on the nature of the research question and the type of knowledge that is needed. Methodology alternatives such as CPI do not replace RCTs, but rather provide additional sources of systematic outcomes information that improve on the anecdotal and informal knowledge base that underlies much of clinical practice. CPI studies used by clinical teams have enormous power to enable health care providers, managed care organizations, payers, and patients to evaluate current practice and improve clinical decision making. These studies answer questions in the real world, where multiple variables and factors can affect the outcomes.

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ORIGINAL ARTICLE

Applying the Clinical Practice Improvement Approach to Stroke Rehabilitation: Methods Used and Baseline Results

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ABSTRACT. Gassaway J, Horn SD, DeJong G, Smout RJ, Clark C, James R. Applying the clinical practice improvement approach to stroke rehabilitation: methods used and baseline results. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S16-33.

Objectives: To describe the methods used and baseline data for the Post-Stroke Rehabilitation Outcomes Project (PSROP).

Design: Prospective observational cohort study.

Setting: Seven inpatient rehabilitation facilities (IRFs) in the United States and New Zealand.

Participants: Consecutive convenience sample of 1291 poststroke rehabilitation patients, age older than 18, who were treated between 2001 and 2003 in 7 IRFs (1161 patients in 6 U.S. IRFs).

Interventions: Not applicable.

Main Outcome Measures: Change in FIM score, change in severity of illness, and discharge destination.

Results: For the U.S. sample, the average age was 66 years, 52% were men, 60% were white, and 23% were black. Medicare was the most frequent payer. Seventy-seven percent of strokes were ischemic, with 43% in the left brain, 44% in the right brain, and 11% bilateral. Mean admission total FIM score was 61, with a mean motor FIM score of 40 and mean cognitive FIM score of 21. Lower FIM scores are associated with higher severity-of-illness scores. Mean rehabilitation length of stay was 18.6 days; 78% of patients were discharged home. At discharge, the average increase in total FIM score was 26, in motor FIM score was 22, and in cognitive FIM score was 4.

Conclusions: This article outlines methods used in the PSROP, provides an overview of participating IRFs, describes the database, and summarizes key characteristics to enable readers of subsequent articles to better interpret study findings and determine generalizability.

Key Words: Outcome assessment (health care); Rehabilitation; Severity of illness index; Stroke.

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THE TERM *BLACK BOX* has been used to describe specific components (interventions) of the stroke rehabilitation process, because specific details about activities used throughout the course of rehabilitation are lacking in rehabilitation literature.[1-6] Stroke rehabilitation practices are customized to meet individual patient needs, which results in variation from one patient to another and from one rehabilitation center to another. Standardized protocols that exist in other areas of medical practice are not common in stroke rehabilitation, which accounts for about 20% of all inpatient rehabilitation admissions. A rationale for the study and detailed literature review substantiating the need to examine rehabilitation processes to improve outcomes for specific types of patients is presented elsewhere.[7]

This article provides an overview of the methods used in a large multisite study of stroke rehabilitation outcomes known as the Post-Stroke Rehabilitation Outcomes Project (PSROP). It was a component of the Rehabilitation Research and Training Center on Medical Rehabilitation Outcomes commissioned by the National Institute on Disability and Rehabilitation Research. The PSROP addressed priority 2: the need for scientific data supporting the effectiveness of rehabilitation treatments for poststroke patients. The article also provides a characterization of the study group, the scope of care received, and an introduction to rehabilitation outcomes realized. It sets the stage for articles that follow, in which the PSROP's findings are reported.

The PSROP introduces to rehabilitation research a genre of research methodology known as clinical practice improvement (CPI).[8] CPI's fit into the pantheon of biomedical and clinical research methodology is described elsewhere.[9] A CPI study is an observational cohort study that entails the acquisition of prospective and retrospective data while not disrupting the natural milieu of treatment. CPI examines what actually happens in the care process and contains several distinct features, some of which are meant to compensate for the shortcomings commonly attributed to observational studies, particularly the ability to account for patient covariates. Because of CPI's methodologic complexity, a significant portion of this article is devoted to how CPI concepts were operationalized in the PSROP.

In the context of rehabilitation, the purpose of a CPI study is to discern the relative contributions of specific interventions and therapies to rehabilitation outcomes taking into account patient differences and other contributing factors. On 1 level, CPI studies are straightforward. They resemble other observational studies that take into account demographic-type patient and setting characteristics that may shape outcomes and determine generalizability. CPI then moves to a level beyond traditional observational approaches to create comprehensive, complex databases that include detailed patient-specific descriptions, severity-of-illness measures, and characterizations of rehabilitation treatments for large samples of patients. Moreover, CPI studies entail extensive clinical staff participation in all phases of study design, data collection, and analyses.

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Table 1: PSROP Participating IRFs

IRF	Location	Site Director	Facility Type	Bed Size
National Rehabilitation Hospital	Washington, DC	B. Conroy, MD	Freestanding	128
University of Pennsylvania Medical Center	Philadelphia, PA	R. Zorowitz, MD	Rehab unit	24
LDS Hospital	Salt Lake City, UT	D. Ryser, MD	Rehab unit	26
Legacy Health System	Portland, OR	F. Wong, MD	Rehab unit	33
Stanford University Hospital	Palo Alto, CA	J. Teraoka, MD	Rehab unit	17
Loma Linda University Medical Center	Loma Linda, CA	M. Brandstater, MD	Rehab unit	40 adult
Wellington & Kenepuru Hospitals	Wellington, NZ	H. McNaughton, MD	Rehab unit	25, 20

Rehab, rehabilitation.

METHODS

Overview

The CPI methodology was central to our approach in the PSROP because it captures in-depth, comprehensive information about patient characteristics (including clinical signs and symptoms), rehabilitation processes of care, and rehabilitation outcomes needed to characterize the process of care and ascertain the contribution of individual rehabilitation processes to outcomes. At the risk of some over simplification, there are 7 components to CPI methodology; the PSROP included the first 5 components, and the sixth and seventh components (validation of findings, incorporation of study findings into care protocols) will be the subject of future work. Each component is described briefly, followed by in-depth descriptions of the first 5 as related to the PSROP:

1. Create a multisite, multidisciplinary project clinical team whose tasks are to (a) identify outcomes of interest, (b) identify individual components of the care process, (c) create a common intervention vocabulary and dictionary, (d) identify key patient characteristics and risk factors, (e) propose hypotheses for testing, and (f) participate in analyses. The multidisciplinary project clinical team builds on theoretic understanding, research evidence to date, existing guidelines, and clinical experience about factors that may influence outcomes.
2. Use the Comprehensive Severity Index (CSI) to control for differences in patient severity of illness, including comorbidities that might otherwise affect outcomes. The CSI is an age- and disease-specific measure of physiologic and psychosocial complexity comprising over 2200 signs, symptoms, and physical findings.
3. Implement an intensive data collection protocol that captures data on patient characteristics, care processes, and outcomes drawn from medical records and study-specific data collection instruments. Data collectors are tested for interrater reliability.
4. Create a study database suitable for statistical analyses.
5. Successively test hypotheses based on questions that motivated the study originally, previous studies, existing guidelines, and, above all, hypotheses proposed by the project clinical team using bivariate and multivariate analyses including multiple regression, analysis of variance (ANOVA), logistic regression, hierarchic models, and other methods consistent with measurement properties of key variables.
6. Validate study findings via an implementation phase that tests the predictive validity of the findings. In this sixth phase, findings from the first 5 steps are implemented and evaluated to determine whether the new or modified interventions replicate results identified in earlier phases.
7. Incorporate validated study findings into standard practice of care. After the validation of specific CPI findings, the findings are ready to be incorporated into care protocols.

As noted, the PSROP did not include the validation implementation or protocol incorporation phases (6 or 7), which will be the subject of future work.

The CPI approach offers a naturalistic view of rehabilitation treatment by examining what actually happens in the care process. It does not alter the treatment regimen to evaluate efficacy of a particular intervention. Moreover, CPI's detailed data on rehabilitation interventions allow researchers to penetrate to the most meaningful level of resolution regarding the types of care rendered—consistent with current knowledge and insights offered by team participants. Thus, the CPI approach can answer study questions and hypotheses initially at a fairly basic level of resolution but also allows researchers to drill down into the data with the help of additional insights offered by clinical team participants.

PSROP Project Clinical Team

The project clinical team provided expert advice to ensure clinical meaningfulness to PSROP activities and analyses. It began as a core group consisting of the medical director from each of 7 participating inpatient rehabilitation facilities (IRFs). This core clinical team developed and implemented patient selection criteria, provided expert advice for data collection instrument development, obtained institutional review board (IRB) approvals at their respective affiliated university or research organization, oversaw the data collection process, and participated in analyses. Over time and depending on project activities/needs, the PSROP clinical team (hereafter "the team") expanded to include representatives of each discipline in stroke rehabilitation. Physical, occupational, speech and language, and recreation therapists; social workers; nurses; and psychologists provided expert advice specific to their fields of expertise. No clinicians or patients received monetary reimbursement for participation. Team members participated in weekly conference calls over much of the 5-year project and specialized subgroups teleconferenced as needed. Frequent team meetings contributed to overall collaboration and investment in the study's processes and findings.

PSROP Facilities

Table 1 lists the 7 (6 in the United States, 1 in New Zealand) IRFs that participated in the PSROP. IRFs were selected based on their willingness to participate and geographic location only. There were no specific criteria for selection, and thus, they are not a probability sample of IRFs in the United States. All facilities are nonprofit. One facility is free-standing; all others are rehabilitation units within an acute care setting. We

Table 2: Stroke CMGs and CMG Groupings by Relative Tier Weights

Stroke CMG Groupings	PSROP* Patients, n (%)	CMG	Stroke CMG Definition			Relative Weights			
			Motor FIM Score	Cognitive FIM Score	Age (y)	Tier 1	Tier 2	Tier 3	None
Mild (CMG 101–103)	148 (11.5)	0101	69–84	23–35	NA	0.478	0.428	0.408	0.386
		0102	59–68	23–35	NA	0.651	0.583	0.555	0.526
		0103	59–84	5–22	NA	0.830	0.743	0.708	0.670
Moderate (CMG 104–107)	511 (39.6)	0104	53–58	NA	NA	0.901	0.807	0.769	0.728
		0105	47–52	NA	NA	1.134	1.016	0.968	0.916
		0106	42–46	NA	NA	1.395	1.249	1.191	1.127
		0107	39–41	NA	NA	1.616	1.447	1.379	1.305
Severe (CMG 108–114)	548 (42.6)	0108	34–38	NA	≥83	1.748	1.565	1.492	1.412
		0109	34–38	NA	<83	1.890	1.693	1.613	1.527
		0110	12–33	NA	≥89	2.028	1.816	1.730	1.638
		0111	27–33	NA	82–88	2.089	1.871	1.783	1.687
		0112	12–26	NA	82–88	2.478	2.220	2.115	2.002
		0113	27–33	NA	<82	2.238	2.004	1.910	1.807
		0114	12–26	NA	<82	2.730	2.445	2.330	2.205

Source: Centers for Medicare and Medicaid Services.[32]
Abbreviation: NA, not applicable (CMG calculation rules for cognitive FIM score apply only to CMG 101–103 and for age apply only to CMG 108–114).
*6.5% PSROP patients have incomplete FIM information.

did not examine facility-specific patient admission criteria for participating IRFs. Each site contributed detailed data for about 200 consecutive poststroke patients for a total of 1291 patients (1161 patients in the United States). The inclusion of 1 international site (New Zealand) provides somewhat different approaches to rehabilitation care and our data confirm these differences. Thus, we elected to report results from New Zealand as compared with the U.S. sample in a separate article.[10] Apart from this article, the remaining articles in this supplement include only the 1161 U.S. patients, and therefore, this article describes information for U.S. patients only.

Each IRF enrolled consecutively admitted patients with stroke who met inclusion criteria; 5 sites began enrolling patients with stroke in March 2001; 2 sites began in June 2001. Facility size and rate of stroke patient admissions determined the duration of the enrollment period. Some sites enrolled 200 poststroke patients in about 8 months; other sites took up to 2 years. No eligible patients were excluded. Patients with stroke from these 6 U.S. IRFs constitute a convenience sample.

Subsequent articles will use specific subsets of the full PSROP database depending on the topic of each article. When subsets are used they are described fully and reasons for inclusion and exclusion of specific patients are provided.

PSROP Patient Selection Criteria

Each participating IRF obtained IRB approval for this observational study and enrolled consecutively admitted patients who met the following inclusion criteria:

(1) Rehabilitation diagnosis of 430 to 438.99, 997.02, or 852 to 853: one of these diagnosis codes was present in the list of *International Classification of Diseases, 9th Revision* (ICD-9),[11] codes in the rehabilitation record.
(2) Age greater than 18 years.
(3) First rehabilitation admission after current stroke, with the principal reason for admission being stroke. The patient may have had previous strokes and previous rehabilitation admissions for previous stroke(s), but this is the first admission for the current stroke. Current stroke must have occurred within 1 year of this rehabilitation admission.
(4) If a patient was transferred to another setting of care (eg, acute care hospital) and returned to the IRF within 30 days, the patient remained a study patient. If a patient transferred to another setting of care and returned to the IRF after 30 days, participation in the study ended on the day of transfer.

There were no exclusion criteria that might otherwise limit the generalizability of findings. Because the study did not entail a new or experimental intervention for which patient consent was needed, there were no refusals or study dropouts and, therefore, no need to compare study participants with study dropouts or need to account for patient selection effects that might otherwise occur. The study obtained informed consent from patients at only 2 sites (1 in the United States, 1 in New Zealand) for their participation in the collection of 6-month postdischarge outcomes at these 2 sites (6-mo outcomes were not collected at the other 5 sites and are not included in this or other articles in this supplement).

We also compared the PSROP study group to a national reference group of stroke patients (*http://eRehabData.com*) to understand better how similar or different PSROP patients are from those who might be found in other IRFs in the nation and to better determine the generalizability of PSROP findings. eRehabData is a subscriber-paid database maintained by the American Medical Rehabilitation Providers Association to monitor national trends and help estimate the programmatic and fiscal impact of federal policy on rehabilitation providers. We used national data only from 2002, mainly because eRehabData was not aggregated across the entire 2001–2003 study, and with only 1 year to choose from, we chose 2002—the midyear of the study period. About 180 rehabilitation providers contributed data to eRehabData for 2002. This is about 15% of all IRFs, but because eRehabData tends to attract larger facilities, its sample of patients is about 20% of the nation's IRF patients.

Data Collection

Three types of study data were obtained from multiple sources either at the point of care or from postdischarge chart review in the IRF: (1) patient characteristics (eg, admission

Table 3: PSROP Patient Characteristics

Characteristics	Site 1 (n=209)	Site 2 (n=198)	Site 3 (n=186)	Site 4 (n=199)	Site 5 (n=206)	Site 6 (n=163)	Site Variation Significance (*P*)	Full Sample (n=1161)	National Data*
Demographic and health plan characteristics									
Mean age (y)	68.0	67.5	65.7	64.4	66.1	64.2	.059†	66.0	69.7
Sex (% male)	49.8	56.1	51.1	58.3	47.6	47.9	.175‡	51.8	46.4
Race (%)							<.001‡		
White	29.2	68.2	50.0	85.9	82.0	27.6		60.6	ND
Black	61.7	7.1	12.9	7.5	1.0	71.2		23.2	ND
Other, including Hispanic	9.1	24.7	37.1	6.6	17.0	1.2		16.2	ND
Payer (%)							<.001‡		
Medicare	56.0	61.1	66.7	50.8	53.4	47.2		56.0	ND
Medicaid	6.7	0.0	15.6	12.1	3.4	23.9		9.7	ND
Commercial	36.8	38.4	9.1	36.2	32.0	28.2		30.5	ND
Self-pay	0.5	0.5	5.9	0.0	7.8	0.6		2.6	ND
Unknown/missing	0.0	0.0	2.7	1.0	3.4	0.0		1.2	ND
Health and functional status characteristics									
Stroke risk factors (%)									
Previous stroke (excludes TIA)	29.2	27.3	32.8	24.6	28.6	24.5	.485‡	27.9	ND
Hypertension diagnosis	82.3	74.6	75.3	75.4	81.1	82.8	.138†	78.6	ND
Diabetes diagnosis	37.8	23.2	32.8	24.6	32.5	33.7	.010†	30.8	ND
Obesity diagnosis	4.8	3.0	4.8	6.0	12.1	1.8	<.001‡	5.6	ND
Smoking history (%)							<.001‡		
Never smoked	53.1	52.0	16.1	43.2	60.7	44.8		45.5	ND
Quit >1y before stroke	21.0	25.3	12.4	25.6	17.5	17.2		20.0	ND
Current smoker	19.1	13.6	23.7	23.0	18.9	33.7		21.6	ND
Unknown/missing	5.3	8.6	47.9	7.5	2.9	4.3		12.5	ND
Type of stroke (%)							<.001‡		
Hemorrhagic	9.1	28.8	42.5	19.1	9.1	26.2		23.2	ND
Ischemic	90.9	71.2	57.5	90.9	80.9	73.8		76.7	ND
Side of stroke (%)							<.001‡		
Right	36.8	46.5	48.9	49.3	39.3	45.4		44.2	42.1§
Left	37.8	43.4	45.7	41.7	44.2	42.3		42.5	42.3§
Bilateral	22.5	7.6	3.8	8.0	12.6	6.8		10.5	3.0§
Unknown	2.9	2.5	1.6	1.0	3.9	5.5		2.8	ND
Location of stroke (%)							<.001‡		
Brainstem/cerebellum	19.1	20.2	11.8	18.6	18.0	23.3		18.4	ND
Subcortical	42.6	31.3	37.6	27.6	31.6	39.9		35.0	ND
Brainstem + subcortical	10.1	2.5	4.3	4.0	5.3	1.8		4.8	ND
Lobar	25.4	38.4	40.3	41.7	42.7	33.1		37.0	ND
Unknown	2.9	7.6	5.9	8.0	2.4	1.8		4.8	ND
Mean admission total FIM score	61.1	64.9	47.4	70.9	54.5	67.9	<.001†	61.0	56.7§
Mean admission motor FIM score	38.3	42.2	31.4	46.7	38.3	43.7	<.001†	40.1	35.5§
Mean admission cognitive FIM score	22.9	22.7	16.1	24.3	16.5	24.0	<.001†	21.0	ND
CMG (%)									
Mild (101–103)	4.3	10.1	3.2	16.1	13.1	8.6	<.001‡	11.5	ND
Moderate (104–107)	35.4	46.5	25.8	57.8	29.1	59.5	<.001‡	39.6	ND
Severe (108–114)	40.7	39.9	67.7	25.1	50.5	28.2	<.001‡	42.5	ND
Mean admission CSI score	19.5	12.8	27.0	15.3	30.0	19.7	<.001†	20.7	ND
Mean no. of diagnosis codes	11.3	10.3	12.8	7.9	15.4	6.0	<.001†	10.8	ND
Stroke symptoms									
Aphasia	19.6	24.2	39.8	18.1	16.5	12.3	<.001‡	21.8	ND
Complete hemiplegia	0.5	0.0	17.7	4.0	15.1	19.0	<.001‡	9.0	ND
Incomplete hemiplegia	91.4	98.0	62.4	86.4	56.8	65.0	<.001‡	77.2	ND
Dysarthria	51.7	41.9	48.5	33.6	56.5	70.6	<.001‡	49.3	ND
Dysphagia	43.1	53.5	71.5	57.8	74.3	52.8	<.001‡	58.8	ND
Ataxia	19.1	15.7	34.4	9.6	61.7	87.7	<.001‡	36.5	ND

Table 3: (Cont'd): PSROP Patient Characteristics

Characteristics	Site 1 (n = 209)	Site 2 (n=198)	Site 3 (n=186)	Site 4 (n=199)	Site 5 (n=206)	Site 6 (n=163)	Site Variation Significance (P)	Full Sample (n=1161)	National Data*
Acute confusion	10.5	22.7	62.4	9.1	25.7	30.1	<.001‡	26.1	ND
Bowel/bladder incontinence	64.1	77.8	83.9	57.3	73.3	55.8	<.001‡	68.9	ND
Prerehabilitation health care									
Mean no. of days from stroke onset to rehabilitation	15.3	13.0	12.9	21.7	10.0	9.1	<.001†	13.8	ND
Mean acute hospital LOS preceding rehabilitation	10.1	9.0	7.5	8.9	6.8	8.2	.006†	8.6	ND

NOTE. For U.S. patients, n=1161.
Abbreviations: ND, no data; TIA, transient ischemic attack.
*National data from eRehabData.com, unweighted data. See text.
†ANOVA.
‡Chi-square test.
§eRehabData impairment group code reports.

severity of illness, functional status measures), (2) process variables (eg, treatments, interventions), and (3) outcome variables (eg, discharge functional status, discharge severity of illness, discharge destination)

Point-of-care data. An important component of CPI is its attention to the process of care that the patient actually receives; it addresses interventions and patient management strategies. CPI typically relies on information contained in patient medical records, which trained data collectors abstract after patient discharge. The team was confident that many identified acute care hospital and rehabilitation study variables could be obtained from existing documentation at their respective sites. However, they strongly believed that existing patient records did not document adequately specific activities and interventions provided by rehabilitation specialists (eg, physical, occupational, and speech therapists); much patient documentation is oriented to the needs of payment or reimbursement systems. The team agreed that the ability to capture details of what rehabilitation specialists do on a daily basis is essential to opening the black box of rehabilitation care and strongly recommended that we first determine how to get all members of the rehabilitation team to describe accurately what they do. Thus, the concept of point-of-care intervention documentation was incorporated into the study design. This initial taxonomy for stroke rehabilitation is described in detail by DeJong et al.[12]

Intervention taxonomy (documentation) development—the black box. Discipline-specific specialty teams with representation from each participating IRF met via teleconferences from June 2000 through January 2001 to conceptualize and then create discipline-specific intervention documentation forms to record activities and interventions used with stroke rehabilitation patients. This iterative process took approximately 9 months, because specialty teams learned quickly that what is practiced in 1 site is often different from other sites. Clinicians also realized that definitions of common terms differ from site to site and practitioner to practitioner. This is the black box of stroke rehabilitation—What is it that therapists and other stroke care clinicians provide to stroke patients? How are activities or interventions defined and described to others?

The study's physicians, nurses, psychologists, social workers, and physical, occupational, recreational, and speech therapists made a first attempt to identify these differences within their practices by creating an intervention documentation form to include a taxonomy of activities used in each clinical area.[12] This work incorporated practices and definitions in existing frameworks—for example, Occupational Therapy Practice Framework and Guide to Physical Therapist Practice and the level of intervention intensity clinicians thought was needed to capture a complete and accurate picture of the contribution made by that discipline to rehabilitation care (beyond what was already contained in traditional medical record documentation). In addition to developing the content of its documentation form, each rehabilitation discipline decided on the frequency with which its form should be completed. The taxonomy provides a format into which clinicians document actual interventions performed with patients. It does not suggest treatment strategies or changes to routine practice.

Intervention documentation forms were standardized for all sites. Because development efforts included representatives from each participating site, the forms contain interventions that may be specific to 1 or more sites but are not used by all. For example, physical therapists in only 1 facility used constrained induced movement therapy, a different site used pet therapy, and several sites used grocery carts as an assistive device. These "unique" interventions are included on each site's form, even though most places do not use them. Therapists were trained to record only what was done in the actual care process at each site.

What is in the black box of stroke rehabilitation? A partial picture of the black box is presented in appendixes 1 through 3, which contain 3 therapy intervention documentation forms. Therapy-specific interventions are associated with therapy-specific activities, and time spent within each is recorded. The physical therapy (PT) form, for example, contains time spent on specific functional activities (eg, sitting, transfers, gait) and interventions (eg, balance training, cognitive training, strengthening, education) used with each activity. In addition, the PT form captures time spent on formal patient assessment and on home and worksite evaluations. In the case of group therapy, therapists record and include the number of patients, therapists, and assistants involved in the group. Other therapy intervention documentation forms (occupational therapy [OT] and speech language pathology [SLP]) also contained in appendixes 2 and 3 follow a similar format to capture the amount of time spent on specific activities (eg, dressing, transfers, community integration for OT; verbal expression, problem solving, pragmatics for SLP) and specific interventions within each activity (eg, strengthening, balance training for OT; visual cueing, auditory

Table 4: PSROP Process Variables

Variables	Site 1 (n=209)	Site 2 (n=198)	Site 3 (n=186)	Site 4 (n=199)	Site 5 (n=206)	Site 6 (n=163)	Site Variation Significance (P)	Full Sample (n=1161)	National Data*
Mean LOS (d)	21.5	18.2	20.5	16.3	20.2	14.4	<.001†	18.6	17.7
Mean PT (median)									
No. of days	15.7 (15)	12.3 (11)	13.5 (12)	13.7 (14)	14.0 (12)	8.0 (7)	<.001†	13.0 (12)	NO
No. of minutes	910 (865)	775 (653)	903 (675)	816 (810)	709 (586)	670 (580)	<.001†	800 (725)	ND
No. of minutes per day	43.1 (43.5)	40.8 (42.0)	42.3 (40.3)	50.0 (50.8)	35.2 (38.6)	45.9 (52.8)	<.001†	42.8 (43.0)	ND
Mean OT (median)									
No. of days	10.6 (10)	11.4 (10)	13.0 (11)	12.5 (13)	12.9 (10.5)	5.5 (4)	<.001†	11.1 (10)	ND
No. of minutes	655 (575)	764 (638)	913 (715)	803 (745)	677 (615)	446 (360)	<.001†	715 (625)	ND
No. of minutes per day	30.8 (30.6)	40.7 (41.2)	42.8 (43.2)	49.3 (50.4)	33.4 (36.9)	31.2 (32.3)	<.001†	38.1 (39.1)	ND
Mean SLP (median)									
No. of days	8.9 (7)	11.3 (10)	11.9 (10)	8.0 (8)	13.5 (11)	ND	<.001†	10.7 (9)	ND
No. of minutes	425 (355)	625 (500)	749 (560)	360 (315)	735 (613)	ND	<.001†	576 (438)	ND
No. of minutes per day	18.8 (20.0)	32.5 (35.5)	34.6 (35.0)	22.5 (20.8)	36.0 (38.6)	ND	<.001†	28.8 (29.5)	ND
Oxygen use (%)	11.0	0	18.3	3.5	53.4	11.0	<.001‡	16.5	ND
Tube feeding use (%)	13.4	7.1	18.8	7.5	43.7	8.6	<.001‡	16.9	ND
Antidepressant use (%)	32.5	39.9	64.0	43.2	68.5	50.3	<.001‡	49.5	ND
Antipsychotic use (%)	5.7	6.6	4.8	3.0	27.7	6.1	<.001‡	9.2	ND
Opioid pain medication use (%)	8.1	24.8	39.3	16.6	33.5	12.3	<.001‡	22.5	ND
Antiseizure medication use (%)	16.3	14.7	29.0	11.1	21.8	15.3	<.001‡	18.0	ND

NOTE. For U.S. patients, n=1161.
*National data from eRehabData.com, unweighted data. See text.
†ANOVA.
‡Chi-square test.

strategies for SLP). One therapy intervention documentation form was completed for each patient treatment session. Rehabilitation clinicians may provide overlapping services as in the case of physical therapists and occupational therapists who may both, for example, provide balance training. In such instances, therapists from each discipline included discipline-specific applications of the overlapping activities and interventions in their taxonomies. The date and time of therapy was included on each intervention documentation form so that frequency of therapy for specific days of the week could be calculated.

In contrast to the therapy disciplines, other rehabilitation disciplines created intervention documentation forms to meet their needs of capturing information not contained in traditional rehabilitation documentation. The physician form, for example, captured time spent in care management discussions, education of patient/family or medical staff, and supportive activities such as contact with payers and dictation of support letters. The social work form contained information about insurance coordination, crisis intervention, team collaboration, and family communication. Physicians and social workers created multi-day forms of patient interaction, with 1 column completed per day, to capture information not documented in traditional documentation. The nursing intervention documentation form was completed for each nursing shift; it contained only information deemed important to the rehabilitation process but not documented elsewhere (eg, frequency of skin checks, frequency and reinforcement of patient/family teaching). Information from these disciplines is not included in this supplement and will be explored in the future to complete the multidisciplinary picture of stroke rehabilitation care. All intervention documentation forms are available on request.

Intervention documentation training and reliability. During a 3-month pilot test period after development of each form, practicing clinicians who worked on form development used their draft forms during patient treatment sessions and solicited impact assessments from clinician colleagues. Discipline-specific weekly teleconferences provided the fornm for clinicians to discuss pilot findings and agree to add, edit, or delete items from the form. Each discipline's form was finalized after this 3-month period (January–March 2001).

IRF clinicians were trained to use intervention documentation forms via discipline-specific train-the-trainer teleconferences attended by a lead clinician in each specialty from each IRF. The project team facilitated this training for each clinical specialty using a training manual that included paper and

electronic copies of the intervention documentation forms, instructions for completing the forms, and definitions for all terms used on the forms. Written case studies were included; 1 case study was used to demonstrate how to complete each form based on a patient scenario. Additional case studies were used to evaluate trainees' understanding of instructions by providing examples of how to use the form for different patient scenarios.

After the telephone training session, each clinical leader conducted on-site training sessions for their coworkers. Teleconferences for each group were held throughout the 2 months following training to provide clinicians the opportunity to discuss implementation issues and ask questions of their peers in other participating institutions.

Each site incorporated auditing of intervention documentation form use into routine site practices. Typically, a second therapist (usually the lead therapist) observed a patient session and completed a separate intervention documentation form based on what was observed. The therapist providing the session completed a form as per protocol and the 2 were compared. The lead therapist reviewed and discussed differences in completion with the practicing therapist.

Intervention documentation form use. Rehabilitation intervention documentation forms were completed for each therapy session and nursing day for each study patient. After patient discharge, completed documentation forms (141,511 forms in all) were transmitted to the project office for optical character recognition interpretation and incorporation into the project database.

Intervention documentation validity. Face validity was built into the therapist intervention documentation forms, because they were developed and used by site therapists as described above. Clinicians came to agree with the content of their respective forms by discussing findings from the pilot test and then agreeing to add, edit, or delete items from the form (content validity).

Predictive validity was assessed as described in other articles[13-16] in this supplement by showing significant effects on outcomes of therapist interventions. For example, the amount of variation explained in discharge FIM score, controlling for patient characteristics (including admission FIM score, severity of illness, demographic factors), was 40% for moderate strokes and 45% for severe strokes. When total time per day spent on PT, OT, and SLP was added, there was no increase in variation explained for discharge FIM, consistent with previous findings by Bode et al.[17] However, when time per day spent in specific PT, OT, and SLP activities was added, the amount of variation explained increased to 52% for moderate strokes and 68% for severe strokes, adding 12% to 23% explanation of variation, respectively, in discharge FIM score.

Postdischarge chart review. Postdischarge chart review was facilitated by the CSI software system that allows for both the input of severity-of-illness data and the creation of auxiliary data modules (ADMs), which are sets of study-specific data elements that are collected in addition to patients' illness severity information. The PSROP clinical team identified and defined all patient, process, and outcome variables to include in the PSROP ADM. Using laptop computers, data collectors at each participating IRF entered chart review data into the CSI software system.

The CSI: disease-specific severity-of-illness data (signs and symptoms). The signature component of the CSI software system is the disease-specific severity system. The CSI is an objective method to define illness severity based on individual signs and symptoms of patients' diseases. Explicit severity criteria were developed by Susan Horn in conjunction with expert clinician panels, originally at the Johns Hopkins Hospital between 1980 and 1992, for each ICD-9-CM diagnosis code or group of similar diagnosis codes. To keep severity criteria up to date with medical practice, the criteria are reviewed and updated via physician panel discussions with each application of the CSI. The CSI defines severity of illness as the physiologic and psychosocial complexity presented to medical personnel due to the extent and interactions of a patient's disease(s).[8,18-24]

Inputs to the CSI include over 2200 disease-specific and age-specific severity criteria including physical findings, historical factors, physiologic parameters, and laboratory results at specified levels of abnormality found in a resident's chart. Treatments provided do not contribute to severity of illness. For example, intubation is not a severity criterion; severity criteria include patient signs and symptoms that led to a clinical decision to intubate (eg, respiratory acidosis, absent breath sounds, cyanosis).

Disease-specific criteria sets are determined by ICD-9-CM codes assigned routinely by trained facility diagnosis-related group (DRG) coding personnel. CSI data collection is performed via retrospective chart review after patient discharge, and thus, all diagnoses assigned by the facility diagnosis coder appear on a front or summary sheet in each patient's chart. The CSI data collector enters the list of diagnosis codes into the CSI software system, which then displays disease-specific criteria to a trained data collector who abstracts the signs and symptoms that address the criteria from the patient's medical record for specified time periods. It is important to note that the existence of a diagnosis does not indicate the extent of the disease. The CSI substantiates the diagnosis and allows for stratification based on documeuted patient signs and symptoms.

The stroke criteria set involves the neurologic, musculoskeletal, cardiovascular, and respiratory systems; vital signs; and laboratory values. The presence of a stroke ICD-9 code (eg, 430 [subarachnoid hemorrhage]) prompts for questions from the stroke criteria set, as listed in appendix 4: highest blood pressure, degree of alertness, ataxia, aphasia, dysarthria, dyspnea, perceptual and sensation impairment, dysphagia, hemiplegia, lesion level, time postinjury, acute confusion, and others. Each criterion is followed by response choices for the data collector to select; possible responses are presented in decreasing order of severity. Responses for the stroke dysphagia question, for example, include unable to swallow liquids, unable to swallow solids, other dysphagia, and no dysphagia. The data collector selects the appropriate response based on information found in the patient's chart; data collectors are trained to select the most severe response (by order of presentation). A disease-specific criteria set exists for each group of similar ICD-9-CM codes; the CSI contains over 5500 criteria sets for specific diagnoses in 5 health care settings (acute care, rehabilitation, ambulatory, long-term care, hospice) with details similar to the stroke criteria set in appendix 4.

In the PSROP, each CSI criterion was answered separately for 3 time periods: admission to rehabilitation (first 24h), discharge from rehabilitation (discharge day), and maximum. (Maximum CSI score covers the full rehabilitation stay, including admission and discharge periods.) The maximum score reflects the most abnormal signs and symptoms, regardless of when they occur during the stay.

CSI severity scores reflect the interactions of various health conditions and diseases, as derived from variables in the disease-specific criteria sets. The CSI severity calculation engine assigns a severity weight to each criterion response, which then contributes to a severity rating for each diagnosis for each review period. To compute the overall severity score for a

Table 5: PSROP Outcome Variables

Variables	Site 1 (n=209)	Site 2 (n=198)	Site 3 (n=186)	Site 4 (n=199)	Site 5 (n=206)	Site 6 (n=163)	Site Variation Significance (P)	Full Sample (n=1161)	National Data*
Complications									
Any mental disorder diagnosis (%)	61.2	50.0	56.5	58.8	63.6	19.0	<.001†	52.6	ND
Depression diagnosis (%)	10.5	11.6	12.4	4.5	29.1	4.9	<.001†	12.5	ND
Pneumonia diagnosis (%)	5.3	10.6	9.7	4.5	17.0	2.5	<.001†	8.4	ND
DVT diagnosis (%)	4.8	2.0	7.0	4.0	11.7	3.7	.001†	5.6	ND
UTI diagnosis (%)	29.2	28.3	35.5	14.1	50.5	12.3	<.001†	28.9	ND
Electrolyte imbalance diagnosis (%)	6.7	29.3	38.7	5.5	32.5	12.9	<.001†	20.9	ND
Anemia diagnosis (%)	30.1	11.1	8.1	6.5	34.0	1.2	<.001†	15.9	ND
Falls (%)	21.5	12.1	12.9	9.6	9.2	12.9	.002†	13.1	ND
Elevated white blood cell count (>11.0 × 10^9/L) (%)	10.1	8.6	26.9	10.6	27.7	8.6	<.001†	15.5	ND
Severity (CSI) during rehabilitation									
Mean maximum CSI score	31.4	19.0	39.7	20.8	47.5	29.6	<.001‡	31.4	ND
Mean increase in severity (maximum − admission)	11.9	6.2	12.7	5.6	17.5	9.9	<.001†	10.7	ND
Mean discharge CSI score	9.8	1.2	16.8	9.1	16.7	9.6	<.001‡	10.5	ND
Mean gross medical improvement (maximum − discharge CSI score)	21.6	17.8	22.8	11.7	30.7	20.0	<.001‡	20.9	ND
Mean net medical improvement (admission − discharge CSI score)	9.7	11.7	10.1	6.1	13.2	10.1	<.001‡	10.2	ND
FIM score									
Mean discharge total FIM score	86.9	91.7	73.4	95.0	84.7	91.3	<.001‡	87.2	76.2
Mean increase in total FIM (discharge − admission score)	26.8	27.0	25.9	24.0	30.1	23.2	<.001‡	26.2	19.5
Mean discharge motor FIM score	60.0	64.8	52.7	66.9	62.4	64.4	<.001‡	61.9	51.8
Mean increase in motor FIM score (discharge − admission)	22.4	22.6	21.4	20.2	24.6	20.4	.003†	21.9	16.3
Mean discharge cognitive FIM score	27.0	26.9	20.7	28.1	21.9	26.9	<.001‡	25.2	
Mean increase in cognitive FIM score (discharge − admission)	4.4	4.2	4.6	3.8	5.2	2.8	<.001‡	4.2	ND
Discharge destination (%)									
Community vs institution							<.001†		
Community discharge includes home	82.3	84.8	73.1	90.0	72.8	82.8		81.0	70.6
Inpatient institutional discharge	17.7	14.1	26.9	10.1	26.2	16.0		18.5	28.5
Died	0.0	1.0	0.0	0.0	1.0	1.2		0.7	0.3
Home only	81.8	80.8	69.4	81.4	72.3	82.8	.003†	78.0	67.5

NOTE. For U.S. patients, n=1161.
*National data from eRehabData.com, unweighted data. See text.
‡ANOVA.
†Chi-square test.

patient, the severity scores for all diagnoses are combined using disease-specific weighting rules that reflect the interaction of the diagnoses. The overall patient severity level is scored on a continuous scale with nonnegative integer values that are not subject to any preset maximum limit. The more abnormal the signs and symptoms, the higher the score, indicating that that patient is more severely ill. For example, a patient with stroke and congestive heart failure (CHF) probably would have a higher severity score than a patient with stroke alone. The CHF diagnosis does not indicate higher severity, but the signs and symptoms that determine acuteness of the disease contribute to the patient's overall severity of illness. If the CHF is controlled and the patient exhibits no abnormal symptoms of the disease, the diagnosis will not contribute to the overall severity score. If, however, the patient exhibits symptoms of CHF such as shortness of breath, abnormal breath sounds, high pulse, low blood pressure, or respiratory acidosis, these symptoms will contribute to the overall CSI score. Thus, to produce the overall CSI score, CSI logic takes into account the interactions of diseases that are present, their severity levels, and the clinical relations of the diseases.

Often a patient is sickest on admission, and thus the admission and maximum CSI scores will be the same. However, when iatrogenic conditions develop, the maximum CSI score becomes larger (more severe) than the admission score; this is referred to as "increase in severity" in the Results section. Discharge CSI scores typically are the lowest because patients have improved and stabilized throughout the rehabilitation stay. Improvements (decreases) in severity scores were measured in 2 ways: (1) gross medical improvement—a decrease from maximum (full stay) CSI score to discharge CSI score—and (2) net medical improvement—a decrease from admission CSI score to discharge CSI score.

Advantages of this approach to measuring severity of illness include disease specificity, based on a concise, carefully chosen set of relevant physiologic characteristics of the particular

disease rather than based on a standard set of physiologic factors applied to all diseases; comprehensive scope, with over 5500 disease-specific severity criteria sets representing all diseases for which there is an ICD-9-CM code; independence of treatments; and ability to measure severity during specified time windows in the care process. The CSI has been validated extensively in many inpatient, ambulatory, and long-term care settings since 1982.[8,18-24]

Validity of the CSI for stroke rehabilitation patients. CSI criteria for stroke were examined and updated by the project clinical team at the beginning of the project to ensure their face validity for stroke rehabilitation patients. Predictive validity of the CSI and its components for stroke rehabilitation patients are shown elsewhere.[13-16,25-28] Although levels of disability are included in the CSI criteria set for patients with stroke, other components of the CSI remain significant in explaining outcomes after controlling for FIM score and other factors. For example, the amount of variation explained in discharge FIM score by demographic factors alone was 3% for patients with moderate strokes and 4% for patients with severe strokes. When the CSI score and its components were added, the amount of variation explained increased to 15% and 24%, respectively, for patients with moderate and severe strokes.

Patient, process, and outcome data. CPI methodology promotes collection of study-specific patient (in addition to severity-of-illness), process, and outcome data elements, identified and defined by the study team into an instrument referred to as the ADM within the CSI software system. The PSROP ADM contained over 200 variables; most contained date and time fields so that they could be associated with other variables in time sequence, and many have numerous data entries. For example, some data related to vital signs, weight, and pain were collected for each day of the rehabilitation stay, so these single variables have as many entries as the length of stay (LOS). The ADM contained an extensive table of selection choices for each variable; however, data collectors were trained to add to the selection table if a response was not present. For example, the durable medical equipment (DME) selection table contained 173 selection options, but data collectors added another 18 options, including elastic shoelaces and plate guard, during data collection. Appendix 5 presents an outline of the stroke ADM; the outline does not include table selection choices. Rehabilitation activities and interventions contained on each discipline's point-of-care intervention documentation forms (see appendixes 1–3) were classified as process variables also but are not included in the ADM outline version in appendix 5.

Patient variables included age, sex, race, payer source, stroke risk factors, type of stroke (hemorrhagic, ischemic), side of stroke (left, right, bilateral), location of stroke (brainstem/cerebellum, subcortical, brainstem and subcortical, lobar, unknown), admission FIM score (total, motor, cognitive, and all components), case-mix group (CMG), acute care hospital LOS, and date and time of stroke symptom onset (which is subtracted from rehabilitation admission date and time to determine the number of days from stroke onset to rehabilitation admission).

Process variables included rehabilitation LOS, therapy intensity, and specific activities and interventions from point-of-care documentation forms; oxygen use; medications during rehabilitation care; incontinence interventions (eg, indwelling catheters); and nutritional interventions (eg, diet type, tube feeding).

Outcome variables in the ADM included discharge FIM scores, death, discharge destination (home, community, institution), repeat stroke, deep vein thrombosis (DVT), electrolyte imbalance, anemia, urinary tract infection (UTI), pneumonia, falls, mental disorders including depression, and elevated white blood cell count.

The functional performance for each study patient on admission to and discharge from inpatient rehabilitation was obtained via retrospective chart review using the study site's recording of FIM scores. We assumed all clinicians providing FIM data within IRFs as part of standard practice were FIM credentialed; no additional documentation of FIM elements was performed for project purposes. The FIM is a widely used measure of performance across 13 motor areas and 5 cognitive areas and has been found to have "acceptably high" interrater reliability.[29-31] The FIM describes a patient's ability to perform various activities of daily living given various levels of assistance. A patient who is independent in completing a task is rated a 7, one who requires only supervision or contact guard is rated a 5, and one who is dependent is rated a 1 for that specific task. In the context of the PSROP project, admission and discharge FIM scores—total, component (motor, cognitive), and subscores (specific domains, eg, dressing upper and lower body, walking, bowel and bladder incontinence, problem solving)—were collected; however, FIM data were incomplete for 6.5% of the sample. FIM ratings also were used to determine "success" or "failure" in a given activity (ie, increasing the component FIM rating to a predetermined level) and to identify a homogeneous group of study patients for comparison of interventions and outcomes (eg, examining differences in interventions among all patients who were rated a 3 in auditory comprehension on admission).

We assigned each study patient to a CMG following stroke CMG definition rules based on motor FIM score, cognitive FIM score, and patient age (table 2).

Chart review training and reliability. Each IRF medical records abstractor completed a 4-day training session during which efficient and accurate collection of chart review data was explained and practiced. After the training session, each data collector underwent a rigorous manual reliability testing process to ensure complete and accurate data collection that went beyond internal data editing features of the CSI (eg, features that prohibit entry of nonsensible values). Reliability monitoring was conducted at 4 points throughout the PSROP to ensure that data accuracy was maintained. An agreement rate of 95% at the criteria level between each data collector and the project training-team reliability person was required for each reliability test.

Database Management

The comprehensive PSROP database contains all point of care and chart review patient data. Patients and facilities are identified by study identification number only and cannot be identified directly or through linked identifiers. The entire CSI database was exported to SAS statistical software, release 8.2,[a] for analysis.

Data Analyses

For categoric variables, we used contingency tables to examine differences in frequencies and conducted bivariate analyses using chi-square tests to examine differences across sites. For continuous measures we used descriptive statistics, such as average, median, quartiles, and amount of variation (standard deviation [SD], range), and conducted bivariate analyses using ANOVA to test differences across sites and Pearson correlation to test associations of continuous variables. A 2-sided P value less than .05 was considered statistically significant.

RESULTS

The study's database includes 1291 patients from 7 inpatient rehabilitation facilities (1161 U.S. patients, 130 New Zealand patients). Tables 3 through 5 provide data on the key patient, process, and outcome characteristics of the U.S. portion of the PSROP study group and for each site separately.

Patient Characteristics

Table 3 provides a profile of the patient characteristics of the U.S. portion of the PSROP (n=1161) and when available, compares study data to national data available in eRehabData.

Demographic and Health Plan Status

Age and sex. The mean age of the study group was 66.0 years, which is somewhat younger than the mean age in the national eRehabData reference group of 69.7 years. The study group's age did not vary significantly across the 6 sites, but differences were borderline ($P=.059$). The study's sex distribution also did not vary significantly across the sites, but there were proportionately more men in our study group (51.8%) than in the national reference group (46.4%).

Race. The largest difference across the sites was the study group's racial distribution, where 2 sites were predominately white and 2 sites were predominately black. The 2 remaining sites had a more even racial distribution.

Payer. Fifty-six percent of the study group had Medicare as the primary payer, and commercial insurance covered about 30%. A small proportion (2.6%) self paid.

Health and Functional Status

Risk factors. The most frequent stroke risk factors in the study group were diagnoses of hypertension (78.6%) and diabetes (30.8%). A small portion (5.6%) of the sample had an obesity diagnosis; most had never smoked (45.5%) or had quit smoking more than a year before stroke (20%). Most did not have a history of alcohol abuse (12% current or former abuse).

Stroke type and location. Most strokes were ischemic in origin (76.7%) and about evenly divided between right (44.2%) or left side (42.5%) of the brain, which is similar to national data (42.1% and 42.3%, respectively). About 10% of the sample had a bilateral stroke (national data, 3.0%). Most strokes were subcortical or lobar, with a smaller percentage of brainstem and cerebellar infarcts.

FIM scores. Mean admission FIM scores (total, 61.0; motor, 40.1) were slightly higher than in the national reference group (56.7 and 35.5, unweighted, respectively). No national reference group data were available for the FIM admission cognitive component (study data, 21.0). Significant differences existed among sites in mean motor, cognitive, and total admission FIM scores (all $P<.001$).

CMGs. All stroke CMGs are represented in the study group, with the largest number in the more severe CMGs. We combined CMGs into mild (CMGs 101–103), 11.5% of the sample; moderate (CMGs 104–107), 39.6% of the sample; and severe (CMGs 108–114), 42.5% of the sample. The 6.5% of patients who had incomplete FIM data were not classified into CMG groups.

Severity of illness (CSI). Severity-of-illness distributions (higher scores indicate more severe) differed significantly among sites for rehabilitation admission (first 24h), ranging from 12.8 to 30.0 ($P<.001$). The number of diagnosis codes per patient correlated significantly with the patient's admission severity score (Pearson $r=.45$, $P<.001$). Site 5 had the highest severity scores, the most diagnoses, and the second lowest functioning scores. Site 2 had the lowest severity scores; however, it did not have the least number of diagnoses or the highest functioning scores.

Stroke symptoms. As might be expected, hemiplegia was found in the majority of the sample (>86%); bowel and bladder incontinence (as measured by admission FIM bowel and bladder scores of ≤4) was also common. Significant differences were seen among sites; most notably, site 3 had more than twice the number of patients with an aphasia diagnosis than most other sites.

Prerehabilitation Health Care

Time from onset of symptoms to rehabilitation. The study group was admitted to rehabilitation an average ± SD of 13.8±20.8 days (median, 7d; range, 0–319d) after the first onset of symptoms. Interim stays in acute care facilities and skilled nursing facilities are included here. Significant differences were found among sites ranging from 9.1 to 21.7 days ($P<.001$).

Acute care hospital LOS. The average LOS in an acute care hospital before rehabilitation admission was 8.6 days; this differed significantly among sites (site average LOS range, 6.8–10.1; $P=.006$). The mean number of days from symptom onset to acute care hospital admission was 1.4±4.2 days (median, 0d; range, 0–51d).

Process Variables

Process variables are detailed by site and overall in table 4.

Rehabilitation LOS. The mean rehabilitation LOS for our study group was 18.6 days, which is slightly higher than the eRehabData national data (17.7d). Three of our sites had mean LOSs of more than 20 days, and 3 had mean LOSs between 14 and 18 days ($P<.001$).

PT, OT, and SLP. Most PSROP patients received at least 1 session of PT (96.7%) or 1 session of OT (94.9%) during their rehabilitation stay. The vast majority of these (94.6%) had at least 1 session of both PT and OT. Only 2.9% of study patients had neither PT nor OT. One site submitted very few SLP intervention documentation forms; therefore, we excluded that site from SLP analyses. After that exclusion, 93.8% of patients received SLP.

Statistically different numbers of days and numbers of minutes of PT, OT, and SLP are seen among study sites. On average, the 3 therapies averaged about 29 to 43 minutes a day when therapy was provided (PT, 42.8min/d; OT, 38.1min/d; SLP, 28.8min/d).

Treatments. Study sites varied significantly in the use of specific treatments, including use of tube feeding for nutritional support and different types of medications. Forty-nine percent of the sample received an antidepressant medication; 9.2% received an antipsychotic. Almost 23% of study patients received opioid pain medications. Differences in medication use by site[25] and differences in the use of tube feeding to provide nutrition[26] are discussed elsewhere.

Outcome Variables

Outcome variables are detailed by site and overall in table 5.

Comorbidities and complications during rehabilitation. More than half the sample (52.6%) had a documented mental disorder: depression (ICD-9 code 311), 12.5%; organic psychotic condition (ICD-9 code 294), 13.6%; and adjustment reaction (ICD-9 code 309), 8.0%.

The most common medical complications during stroke rehabilitation in our study sample were UTIs (28.9%), anemia (15.9%), and electrolyte imbalances (20.9%); DVTs occurred least frequently (5.6%). We found significant site variation in all measured outcome variables ($P\leq.003$).

Severity of Illness (CSI)

Increase in severity during rehabilitation. Some patients (11%) had an increase in CSI score during the rehabilitation stay, indicating that their illness severity increased during the stay from what it was at admission. The mean increase in severity for the full sample was 10.7 (20.7 on admission, 31.4 at maximum); significant site variation was found ($P<.001$).

Discharge severity and change in severity from admission to discharge. Significant differences were found among sites in gross medical improvement (decrease from maximum [full-stay] CSI score to discharge CSI score) and net medical improvement (decrease from admission CSI score to discharge CSI score; ANOVA, $P<.001$).

FIM Scores

Discharge FIM score and change in FIM scores from admission to discharge. The mean discharge total and motor FIM scores for the study population were higher than for the national sample (total FIM: 87.2 vs 76.2; motor FIM: 61.9 vs 51.8, respectively); larger increases in total and motor FIM scores also were seen in the study sample (total FIM: 26.2 vs 19.5; motor FIM: 21.9 vs 16.3, respectively). Data for cognitive FIM components are not provided in the national data. Study sites differed significantly in mean motor, cognitive, and total discharge FIM scores (all $P<.001$).

Low FIM scores and high severity scores. As seen in table 3, the 2 facilities (sites 3 and 5) that had the lowest functioning patients, as measured by admission FIM scores, also had the highest severity ("sickest") patients, as measured by the highest admission CSI scores.

Rehabilitation Discharge Destination

Most study patients (81%) were discharged from the rehabilitation center to a community setting and the vast majority of these were to the resident or family home (78%). This compares with national statistics of 70.6% and 67.5%, respectively. The study sample had about double the percentage of deaths (0.7%) when compared with the national sample (0.34%).

DISCUSSION

The wide-ranging effects of stroke are a challenge for determining the right match between a stroke survivor's needs and the appropriate rehabilitation services. Failure to find the right fit can result in too little or too much care for a patient's individual needs. We cannot clinically and fiscally allocate appropriate rehabilitation services for every patient with stroke without stronger detailed scientific evidence showing the effectiveness of poststroke rehabilitation interventions. By using the CPI approach, the PSROP assembled a comprehensive database providing the opportunity to examine the complex interplay of patient and process factors and their impact on stroke patient outcomes.

Because of the central role played by the project team in all aspects of CPI, this approach can be characterized as a form of participatory action research—a bottom-up approach that values the participation of those actually engaged in the care-providing process and garners their participation in implementing study findings. CPI encourages new findings, even those that challenge conventional wisdom and long-standing practice.

During this study, there were extraordinary contributions of clinical expertise and time to develop new intervention documentation forms by clinical team members at each IRF. The inclusive nature of the CPI approach retained clinician participation for more than 5 years with no financial rewards. Physicians, therapists, and social workers, among others, realized that better understanding of the details of everyday practice (obtained from data, not expert consensus) and the association of these details with patient outcomes can make great contributions to better outcomes for patients with stroke and better training and practice techniques for clinicians. The level of detail about rehabilitation care that became a part of the supplemental intervention documentation forms had never been documented before and provided tremendous potential to discover treatments that are best for specific patient types.

The CSI enabled us to go beyond controlling only for stroke severity: it allowed us to control for many complex comorbidities common to patients with stroke (particularly those with severe stroke), reflecting more accurately the realities of clinical practice. The strength of the CSI's mechanism for compensating or adjusting for differences among patients allows for a more powerful assessment of the effectiveness of therapeutic interventions. The CSI's use of very specific, disease-oriented questions produced a highly sensitive measure of severity that could not be produced by using diagnosis and/or procedure codes alone or a limited, fixed set of physiologic criteria no matter what the underlying diagnoses may be. Diagnosis codes indicate existence of disease; they do not indicate extent of disease.

Study sites with higher severity-of-illness scores tended to have lower functioning scores (FIM) on admission. The pattern continued at discharge where again, sites with higher discharge severity scores tended to have lower functional scores. Similarly, study sites with lower severity scores tended to have higher-functioning patients (see tables 3, 5). Study sites that had higher severity-of-illness scores also had higher use of more intensive treatments such as oxygen use and nutritional tube feedings (see table 4).

Limitations

CPI methodology relies on the expertise of participating facility clinicians to guide the development of high-level study hypotheses and identify critical data elements to study. As such, these clinicians are aware of study data elements as they provide care and complete point-of-care intervention documentation forms or perform routine documentation practices. This could be construed as introducing treatment bias; however, the number of clinicians who participated in the development of study instruments was a very small subset of all clinicians who cared for over 1200 stroke rehabilitation patients in 7 facilities in 2 countries. Intervention documentation forms and project hypotheses were designed to capture descriptions of actual practice, not to alter practice patterns. In addition, the novelty of attention to specific study questions would wane over the course of an extended patient enrollment period (8mo to 2y, depending on site size and stroke volume).

As much as supplemental point-of-care intervention documentation forms provide an unprecedented level of detail about rehabilitation interventions, they also have intrinsic limitations. Add-on documentation to traditional IRF practices increases the documentation burden of front-line staff and allotted documentation time may not be sufficient to ensure complete documentation of both. Intervention documentation form training was conducted via a train-the-trainer approach using a lead clinician in each rehabilitation discipline in each IRF. Thus, the training of most clinicians depended on the expertise and time availability of the IRF trainers. Monitoring of documentation accuracy became an obligation of each IRF. The project clinical team received reports of IRF auditing processes and findings but did not intervene directly to determine the level of accuracy of

documentation form completion. The project also depended on each IRF to package all intervention documentation forms and send them to the project office for scanning into the project database. Despite these limitations, significant variation in outcomes was found because of differences in time spent per day in various therapy activities.[14-16]

The original intent of the PSROP was to collect data from both the acute care hospital and rehabilitation records to cover the full poststroke course for each patient. However, budgetary and time constraints, as well as lack of convenient access to acute care charts, resulted in complete data from acute care hospital records being collected for only a small portion of the study population. In the end, data collection focused primarily on the rehabilitation stay. This led to lack of ability to control for some patient and process variables that could affect functional outcomes—for example, initial stroke severity (CSI score in acute care), blood pressure, temperature, and glucose levels in the early poststroke period; acute care complications such as seizures; and details of therapies and medications received during acute care hospitalization.

In the initial planning stages, efforts were made to identify and use an objective, validated measure of initial stroke severity (ie, the National Institutes of Health Stroke Scale), but no standard measure was in use across all participating IRFs. Hence, we did not include such a measure. We also did not assess admitting criteria for each IRF, which may have had an effect on types of patients admitted and, thus, types of patients included in the study.

A physiologic severity indexing system, such as the CSI, is limited by data availability. Credentialed DRG coding personnel at each facility assign ICD-9-CM codes as part of standard operating IRF procedures; it is these codes that determine reimbursement. We did not evaluate the credentialing procedures, nor did we audit code assignment. However, the difference in average number of ICD-9-CM codes assigned in facilities (range, 6−15) is curious. A smaller number of ICD-9-CM codes may result in lower severity of illness when using a system that is built on ICD-9-CM coding. Indeed, the facility with the highest average number of ICD-9-CM codes (15.4) did have the highest mean severity-of-illness score (30). However, the facility with the lowest average number of ICD-9-CM codes (6.0) did not have the lowest mean severity scores; there were 2 facilities with lower admission and maximum mean severity scores. If laboratory tests are not ordered, findings are not clearly reported, or complications are not documented, the severity or incidence rate for the related conditions will be lower. The incidence and type of test ordering and availability of information was not uniform across sites and could account for a significant portion of the site variability reported in CSI scores. However, the CSI and/or its components were significant predictors of various outcomes.[13-16,25-28]

Lack of a defined time point for measurement of function after stroke was another limitation of the study. Ideally, the FIM score would be measured at some predetermined endpoint (eg, 90d after stroke onset) for all patients. Use of the discharge FIM scores is less satisfactory, because discharge itself is affected by institutional policies, patient preferences, socioeconomic concerns, insurance coverage, rate of recovery, and other variables.

The rehabilitation setting database created from this project is extremely rich in detail. Of course, this leads to an additional limitation—not all data are reported in this supplement. We plan future publications that capture descriptions and contributions (intervention documentation) of other members of rehabilitation care teams, such as nurses and social workers.

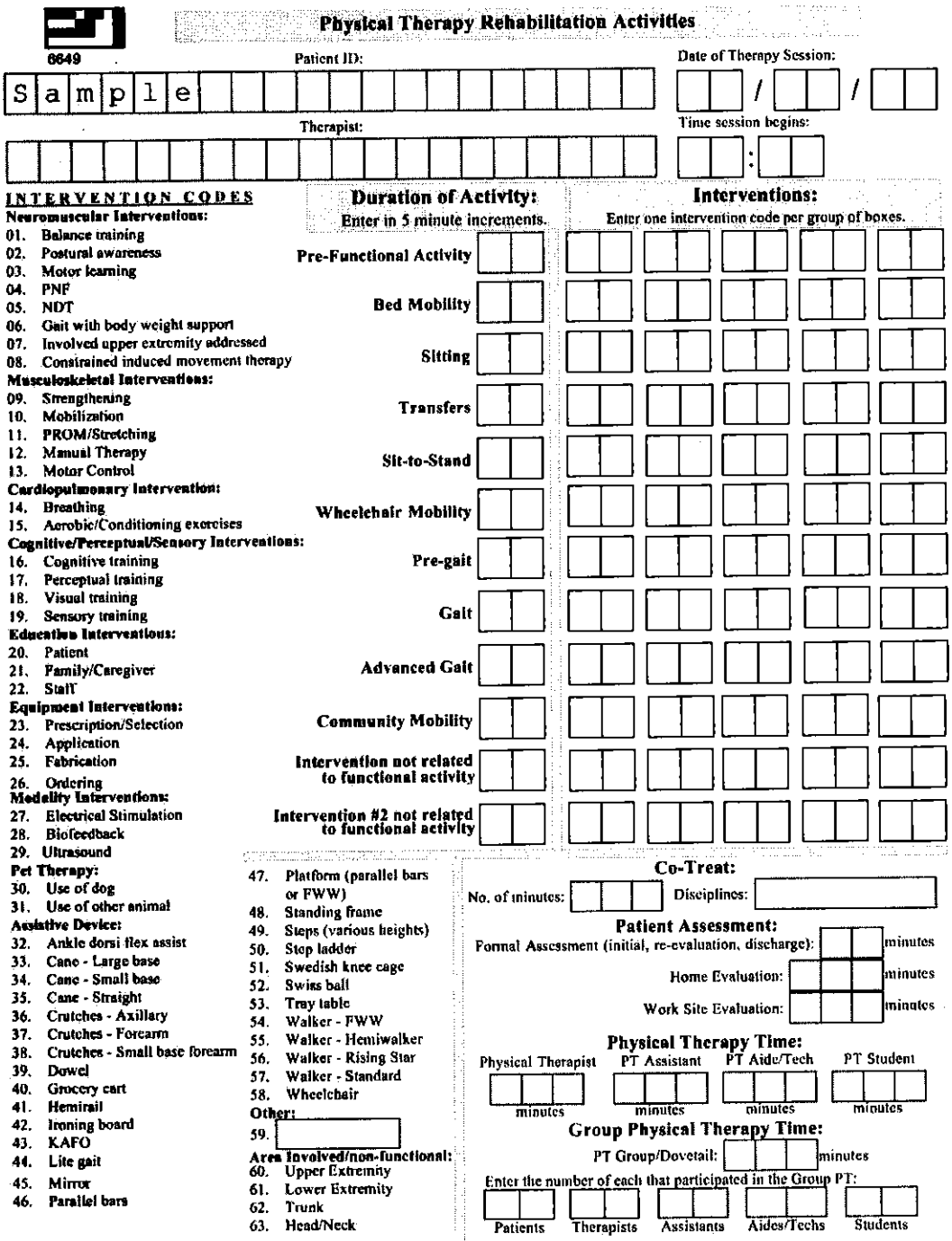
Despite these limitations, having micro-level data provided the ability to focus on the individual patient level to explore reasons for our findings. The PSROP was the first application of CPI methodology to a rehabilitation population and process. As with any new application of a process, a certain amount of trial and error occurred. This knowledge will accrue to subsequent CPI studies for other impairment categories and settings, allowing significant incremental improvements in the efficiency, methodology, and reliability of such studies. The knowledge learned also will facilitate completion of CPI process steps 6 and 7 (validation implementation, protocol incorporation) in future work.

CONCLUSIONS

The PSROP created a comprehensive database to assess the importance of such stroke variables as sex, race, severity of illness, baseline level of functioning, and various therapy interventions on patient-centered outcomes. The PSROP allowed us to describe the duration, intensity, and components of treatment regimens. In addition, the PSROP allowed us to discover treatment practices that are associated with better outcomes for patients with various levels of impairment after stroke. These include findings about medications, PT, OT, SLP, timing of rehabilitation, and nutritional support. Subsequent articles in this supplement describe these findings in detail.[13-16,25-28]

Acknowledgments: We acknowledge contributions of collaborators at each clinical site represented in the Post-Stroke Rehabilitation Outcomes Project: Brendan Conroy, MD (Stroke Recovery Program, National Rehabilitation Hospital, Washington, DC); Richard Zorowitz, MD (Department of Rehabilitation Medicine, University of Pennsylvania Medical Center, Philadelphia, PA); David Ryser, MD (Neuro Specialty Rehabilitation Unit, LDS Hospital, Salt Lake City, UT); Jeffrey Teraoka, MD (Division of Physical Medicine and Rehabilitation, Stanford University, Palo Alto, CA); Frank Wong, MD, and LeeAnn Sims, RN (Rehabilitation Institute of Oregon, Legacy Health Systems, Portland, OR); Murray Brandstater, MD (Loma Linda University Medical Center, Loma Linda, CA); and Harry McNaughton, MD (Wellington and Kenepuru Hospitals, Wellington, NZ). We also acknowledge the role of Alan Jette, PhD (Rehabilitation Research and Training Center on Medical Rehabilitation Outcomes, Boston University, Boston, MA).

APPENDIX 1: PT INTERVENTION DOCUMENTATION FORM*



Physical Therapy Rehabilitation Activities

8649

Patient ID: Sample

Date of Therapy Session: / /

Therapist:

Time session begins: :

INTERVENTION CODES

Neuromuscular Interventions:
01. Balance training
02. Postural awareness
03. Motor learning
04. PNF
05. NDT
06. Gait with body weight support
07. Involved upper extremity addressed
08. Constrained induced movement therapy

Musculoskeletal Interventions:
09. Strengthening
10. Mobilization
11. PROM/Stretching
12. Manual Therapy
13. Motor Control

Cardiopulmonary Intervention:
14. Breathing
15. Aerobic/Conditioning exercises

Cognitive/Perceptual/Sensory Interventions:
16. Cognitive training
17. Perceptual training
18. Visual training
19. Sensory training

Education Interventions:
20. Patient
21. Family/Caregiver
22. Staff

Equipment Interventions:
23. Prescription/Selection
24. Application
25. Fabrication
26. Ordering

Modality Interventions:
27. Electrical Stimulation
28. Biofeedback
29. Ultrasound

Pet Therapy:
30. Use of dog
31. Use of other animal

Assistive Device:
32. Ankle dorsi flex assist
33. Cane - Large base
34. Cane - Small base
35. Cane - Straight
36. Crutches - Axillary
37. Crutches - Forearm
38. Crutches - Small base forearm
39. Dowel
40. Grocery cart
41. Hemirail
42. Ironing board
43. KAFO
44. Lite gait
45. Mirror
46. Parallel bars
47. Platform (parallel bars or FWW)
48. Standing frame
49. Steps (various heights)
50. Stop ladder
51. Swedish knee cage
52. Swiss ball
53. Tray table
54. Walker - FWW
55. Walker - Hemiwalker
56. Walker - Rising Star
57. Walker - Standard
58. Wheelchair
Other:
59.

Area Involved/non-functional:
60. Upper Extremity
61. Lower Extremity
62. Trunk
63. Head/Neck

Duration of Activity: Enter in 5 minute increments.

Interventions: Enter one intervention code per group of boxes.

- Pre-Functional Activity
- Bed Mobility
- Sitting
- Transfers
- Sit-to-Stand
- Wheelchair Mobility
- Pre-gait
- Gait
- Advanced Gait
- Community Mobility
- Intervention not related to functional activity
- Intervention #2 not related to functional activity

Co-Treat:
No. of minutes: Disciplines:

Patient Assessment:
Formal Assessment (initial, re-evaluation, discharge): minutes
Home Evaluation: minutes
Work Site Evaluation: minutes

Physical Therapy Time:

Physical Therapist	PT Assistant	PT Aide/Tech	PT Student
minutes	minutes	minutes	minutes

Group Physical Therapy Time:
PT Group/Dovetail: minutes
Enter the number of each that participated in the Group PT:

Patients	Therapists	Assistants	Aides/Techs	Students

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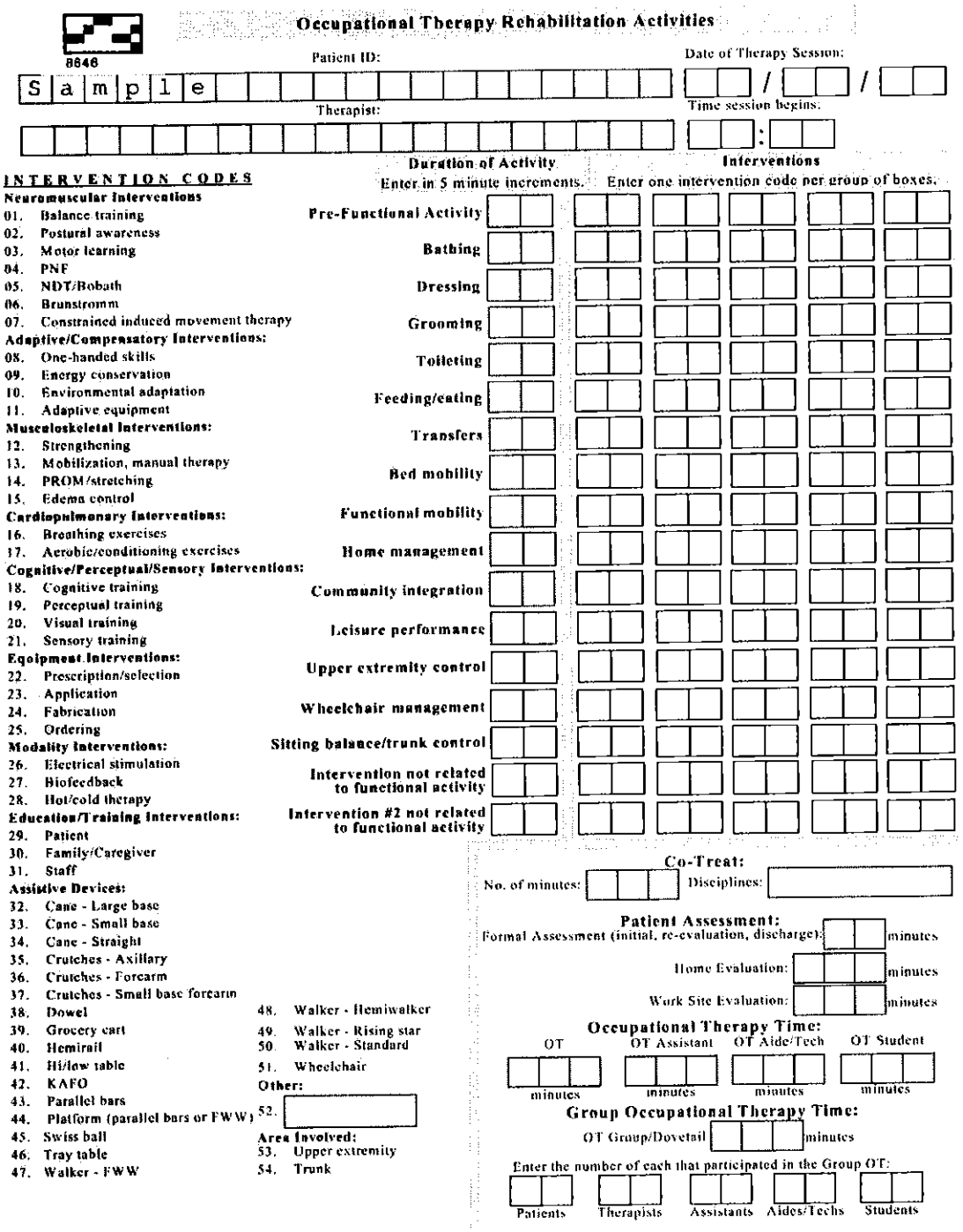
Abbreviations: FWW, front-wheel walker; KAFO, knee-ankle-foot orthosis; NDT, neurodevelopmental treatment; PNF, proprioceptive neuromuscular fasciculation; PROM, passive range of motion.
*Definition of terms available on request.

APPENDIX 2: OT INTERVENTION DOCUMENTATION FORM*



Occupational Therapy Rehabilitation Activities

8846

Patient ID: Sample

Date of Therapy Session: / /

Therapist:

Time session begins: :

INTERVENTION CODES

Neuromuscular Interventions
01. Balance training
02. Postural awareness
03. Motor learning
04. PNF
05. NDT/Bobath
06. Brunstromm
07. Constrained induced movement therapy

Adaptive/Compensatory Interventions:
08. One-handed skills
09. Energy conservation
10. Environmental adaptation
11. Adaptive equipment

Musculoskeletal Interventions:
12. Strengthening
13. Mobilization, manual therapy
14. PROM/stretching
15. Edema control

Cardiopulmonary Interventions:
16. Breathing exercises
17. Aerobic/conditioning exercises

Cognitive/Perceptual/Sensory Interventions:
18. Cognitive training
19. Perceptual training
20. Visual training
21. Sensory training

Equipment Interventions:
22. Prescription/selection
23. Application
24. Fabrication
25. Ordering

Modality Interventions:
26. Electrical stimulation
27. Biofeedback
28. Hot/cold therapy

Education/Training Interventions:
29. Patient
30. Family/Caregiver
31. Staff

Assistive Devices:
32. Cane - Large base
33. Cane - Small base
34. Cane - Straight
35. Crutches - Axillary
36. Crutches - Forearm
37. Crutches - Small base forearm
38. Dowel
39. Grocery cart
40. Hemirail
41. Hi/low table
42. KAFO
43. Parallel bars
44. Platform (parallel bars or FWW)
45. Swiss ball
46. Tray table
47. Walker - FWW
48. Walker - Hemiwalker
49. Walker - Rising star
50. Walker - Standard
51. Wheelchair

Other:
52.

Area Involved:
53. Upper extremity
54. Trunk

	Duration of Activity (Enter in 5 minute increments.)	Interventions (Enter one intervention code per group of boxes.)
Pre-Functional Activity		
Bathing		
Dressing		
Grooming		
Toileting		
Feeding/eating		
Transfers		
Bed mobility		
Functional mobility		
Home management		
Community integration		
Leisure performance		
Upper extremity control		
Wheelchair management		
Sitting balance/trunk control		
Intervention not related to functional activity		
Intervention #2 not related to functional activity		

Co-Treat:
No. of minutes: Disciplines:

Patient Assessment:
Formal Assessment (initial, re-evaluation, discharge): minutes
Home Evaluation: minutes
Work Site Evaluation: minutes

Occupational Therapy Time:

OT	OT Assistant	OT Aide/Tech	OT Student
minutes	minutes	minutes	minutes

Group Occupational Therapy Time:
OT Group/Dovetail minutes

Enter the number of each that participated in the Group OT:

Patients	Therapists	Assistants	Aides/Techs	Students

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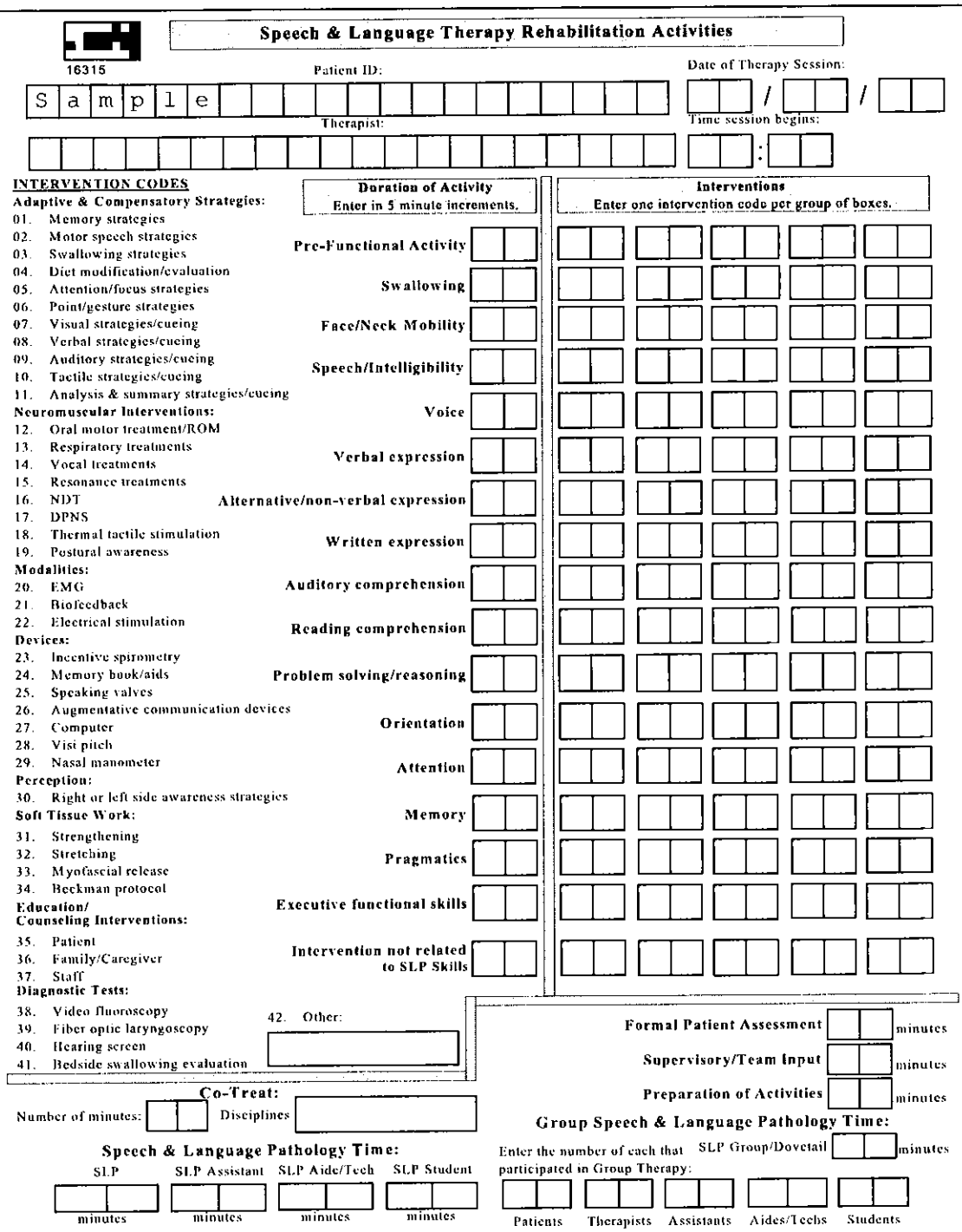
APPENDIX 3: SLP INTERVENTION DOCUMENTATION FORM*



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Abbreviations: DPNS, direct pharyngeal nerve stimulation; EMG, electromyography; ROM, range of motion.
*Definition of terms available on request.

APPENDIX 4: CSI CRITERIA SET FOR STROKE

Criteria	Selection Choice Options (from highest to lowest severity)
Three-dimensional impairment array	
Degree of impairment	Complete or incomplete high or low quadriplegia, complete or incomplete hemiplegia, upper or lower monoplegia
Ambulatory status	Ambulatory, nonambulatory
Time postinjury	Number of days or number of weeks
Neurologic status	Unresponsive, acute confusion, chronic confusion
Lowest Glasgow Coma Scale score	
Degree of alertness	Coma, stupor, lethargic, drowsy, alert
Seizures	Status epilepticus, grand mal seizure, focal or petit mal seizure focal tremors
Pupil reaction	Bilateral pupil dilation, unilateral pupil dilation
Coordination/balance	Severe ataxia, moderate-mild ataxia, dizziness, vertigo, unsteady on feet, clumsiness, other altered coordination
Sensation alteration	Complete loss of sensation, paresthesia, dysthesia, other sensation alteration
Aphasia	Global aphasia, severe-moderate aphasia, mild aphasia
Dysarthria	No speech, incomprehensible sounds, dysphonia, other dysarthria
Dysphagia	Unable to swallow solids, unable to swallow liquids, other dysphagia
Nausea/vomiting	Persistent vomiting, other vomiting, nausea
Headache	Intense headache, moderate to severe headache, other headache
Dyspnea	Dyspnea at rest, dyspnea on exertion, breathing difficulties
Rales	Rales >50% of lung fields, rales ≤50% of lung fields
Breath sounds	Absent breath sounds in >50 of lung fields, decreased breath sounds in >50% of lung fields, decreased breath sounds in ≤50% of lung fields
Apnea	Apnea, no apnea

APPENDIX 4: CSI CRITERIA SET FOR STROKE (cont'd)

Criteria	Selection Choice Options (from highest to lowest severity)
Perceptual impairment	Acute decline in perceptual function, chronic perceptual impairment requiring internal or external cues, intermittent perceptual limitations
EKG rhythm	Ventricular tachycardia, >6 PVCs/min, SVT, bigeminy, trigeminy, quadrigeminy, atrial fibrillation, PACs, other ectopics
Highest blood pressure, systolic and diastolic	
Lowest systolic blood pressure	
Highest pulse	
Lowest pulse	

Abbreviations: EKG, electrocardiogram; PAC, premature atrial contraction; PVC, premature ventricular contraction; SVT, supraventricular tachycardia.

APPENDIX 5: PSROP ADM OUTLINE

I. Patient demographics/history
  1. Race, religion
  2. Cardiovascular history
  3. Alcohol, smoking, illicit drug use/history
  4. Before stroke: ambulation capability, ADLs, DME, medication
  5. Education level, career, financial stressors
  6. Acute care LOS

II. Rehabilitation information
  1. Stroke details
    A. Onset of symptoms (date, time)
    B. First medical contact (date, time, location)
    C. Stroke details (side, type/location of stroke, vascular involvement, cerebral edema)
  2. Therapies missed (date, time, reason), oxygen increased requirements during therapy
  3. Mental status assessment
  4. Vitals from nursing progress notes/flow sheets
    A. Daily high temperature, high/low systolic BP, high/low diastolic BP, weight
    B. Suction type/frequency
    C. Lowest oxygen saturation, maximum oxygen requirements
    D. Pain (0–10 scale, location)
    E. Diarrhea/constipation
  5. Bladder and bowel training programs
    A. Indwelling catheter (insertion/removal dates)
    B. Intermittent catheter (insertion/removal dates)
    C. Postvoid residual measurements (each date)
    D. Bladder scan date
    E. Prompted bladder program date
    F. Prompted bowel program date

APPENDIX 5: PSROP ADM OUTLINE (cont'd)

6. Respiratory management
   A. Ventilator start/stop date/time
   B. Tracheostomy start/stop date/time
   C. Sleep apnea
   D. CPAP/BiPAP
7. Nutrition
   A. Dietary consult dates
   B. Type of diet
   C. By mouth nutritional beverage/supplement
   D. Tube feedings
   E. Calorie counts
8. Complications
   A. Pressure ulcer assessment (date, location, stage, width, length, depth, tissue type)
   B. Deep vein thrombosis (date, location)
   C. Fall (date, time, type)
   D. Physical restraints/electronic monitoring (start/stop date/time)
   E. Elevated white blood cell count $>11.0\times10^9$/L (date, value)
9. Medications (varying levels of dosing information based on drug type)
10. Laboratory test results (albumin, pre-albumin, INR, homocysteine, serum drug levels)
11. FIM scores (all FIM data for admission, discharge, and other times of completion)
12. Family/caregiver assessment
   A. Caregivers (who)
   B. Physical support available from caregivers after discharge (some, 24 hours)
   C. Supervision available from caregivers after discharge (some, 24 hours)
13. Discharge
   A. Projected location
   B. Actual location
   C. Reason different
   D. Recommended discharge therapy programs
   E. Support programs
   F. Acute care DRG (if returned to acute care)
   G. Reason for discharge to acute care
   H. Discharge DME

Abbreviations: ADLs, activities of daily living; BiPAP, bilevel positive airway pressure; BP, blood pressure; CPAP, continuous positive airway pressure; INR, international normalized ratio.

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ORIGINAL ARTICLE

Timing of Initiation of Rehabilitation After Stroke

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ABSTRACT. Maulden SA, Gassaway J, Horn SD, Smout RJ, DeJong G. Timing of initiation of rehabilitation after stroke. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S34-40.

Objective: To study associations between days from stroke symptom onset to rehabilitation admission and rehabilitation outcomes, controlling for a variety of confounding variables.

Design: Observational cohort study of 200 consecutive post-stroke rehabilitation patients in each of 6 inpatient rehabilitation facilities.

Setting: Six U.S. inpatient rehabilitation hospitals.

Participants: Patients (N=969) with moderate or severe strokes who had days from stroke symptom onset to rehabilitation admission recorded in their medical records.

Interventions: Not applicable.

Main Outcome Measures: Discharge total FIM, discharge motor FIM, discharge activities of daily living (ADL) FIM, and discharge mobility FIM scores, as well as rehabilitation length of stay (LOS).

Results: Fewer days from stroke symptom onset to rehabilitation admission was associated significantly with better functional outcomes: higher total, motor, mobility, and ADL discharge FIM scores, controlling for confounding variables. For severely impaired patients with stroke in case-mix groups (CMGs) 108–114, the relation was strongest, with F statistics greater than 24.1 for each functional outcome. For patients with moderately severe stroke in CMGs 104–107, fewer days from stroke symptom onset to rehabilitation admission was associated significantly with shorter rehabilitation LOS.

Conclusions: Fewer days from stroke symptom onset to rehabilitation admission is associated with better functional outcomes at discharge and shorter LOS.

Key Words: Cerebrovascular accident; Clinical practice variations; Rehabilitation; Stroke; Treatment outcomes.

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STROKE IS COMMON and is a leading cause of disability. Mortality rates from stroke have been declining,[1,2] resulting in more people living with residual disability.[3-5] It is well documented in the literature that rehabilitation plays an important role in functional recovery of stroke survivors, providing quantifiable benefits beyond the natural recovery that occurs without any targeted therapy.[3,6-8]

Unfortunately, existing studies of stroke rehabilitation outcomes are neither clear nor consistent,[3] and debate continues over effectiveness of stroke rehabilitation programs.[9-11] Many rehabilitation providers argue that the acute care hospital payment system encourages acute care providers to discharge patients to rehabilitation before they are medically stable. However, early mobilization and more aggressive rehabilitation are components of stroke unit care thought to contribute to improved outcomes.[12-17]

Optimal timing of rehabilitation after stroke remains controversial. It is an important question to answer because it is modifiable, unlike other predictors of functional recovery after stroke (eg, age, premorbid function). Several studies provide evidence for the benefit of early rehabilitation compared with later intervention in patients with stroke.[3,6,12,18-20] However, interpretation of these studies is limited by heterogeneous definitions, study designs, and methods. For example, early rehabilitation may mean starting rehabilitation anywhere from 3 to 30 days after stroke.[6] Johnston and Keister[21] found that the positive correlation between early rehabilitation and improved functional outcomes disappeared when key patient characteristics, such as functional status on admission, were controlled for. The problem is compounded further by variation in type and severity of strokes, variation in rehabilitation procedures in different settings, and incomplete, vague, or ambiguous documentation of what constitutes each type of therapy.[22,23]

The question of how soon to start rehabilitation after stroke is relevant also in light of recent theories regarding neural responses to injury. Surrounding a cerebral infarct is a zone of cells that potentially are salvageable but are more vulnerable to injury poststroke (the ischemic penumbra). These cells may or may not recover, depending on a number of physiologic factors.[24] Based on animal studies and human imaging studies, there is evidence for neural reorganization thought to be dependent on some form of synaptic plasticity.[24-26] There may be increased potential for cortical plasticity in the 7 to 18 days after injury (animal literature),[27,28] suggesting a critical period to obtain the best recovery after stroke.[24]

On the other hand, rehabilitation in the very early stages after stroke theoretically may harm vulnerable cells via oxidative and/or metabolic stress in concert with reperfusion injury. Many patients show extension of the infarct area by imaging within the first few days after stroke.[29] Even so, increases in infarct volume have not always been shown to correlate predictably with functional outcomes. Two studies in experimentally lesioned animals report a paradoxic exacerbation of brain damage with concomitant enhancement of recovery of function after early rehabilitative interventions.[30,31]

A detailed literature review substantiating the need to examine rehabilitation processes to improve outcomes for specific

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types of patients is presented elsewhere.[32] The purpose of the analyses presented here was to study the associations between days from onset of stroke symptoms to rehabilitation admission and rehabilitation outcomes, controlling for a variety of confounding variables based on data from the Post-Stroke Rehabilitation Outcomes Project (PSROP).

METHODS

The clinical practice improvement (CPI) methodology was used in the PSROP because it captures in-depth, comprehensive information about patient characteristics (including clinical signs and symptoms), rehabilitation processes of care, and rehabilitation outcomes needed to characterize the process of care and ascertain the contribution of individual rehabilitation processes to outcomes.[33] An in-depth description of the study's methods, including issues of validity and reliability, can be found in Gassaway et al[33] in this supplement. In this article, we provide only a summary of the study's extensive methods to help interpret the findings reported here.

PSROP Facilities

Six U.S. inpatient rehabilitation facilities (IRFs) participated in the PSROP and were selected based on geographic location and their willingness to participate; they are not a probability sample of IRFs in the United States. Each site contributed detailed data on about 200 consecutive poststroke patients, for a total of 1161 patients. Patients with stroke from these 6 IRFs constitute a convenience sample.

PSROP Patient Selection Criteria

Each participating IRF obtained institutional review board approval for this observational study and enrolled consecutively admitted patients who met the following inclusion criteria:

(1) Rehabilitation diagnosis of 430 to 438.99, 997.02, or 852 to 853: one of these diagnosis codes was present in the list of *International Classification of Diseases, 9th Revision*,[34] codes in the rehabilitation record.
(2) Age greater than 18 years.
(3) First rehabilitation admission after the current stroke, with the principal reason for admission being stroke. The patient may have had previous strokes and previous rehabilitation admissions for previous stroke(s), but this was the first admission for the current stroke. Current stroke must have occurred within 1 year of this rehabilitation admission.
(4) If a patient was transferred to another setting of care (eg, acute care hospital) and returned to the IRF within 30 days, the patient remained a study patient. If a patient transferred to another setting of care and returned to the IRF after 30 days, participation in the study ended on the day of transfer.

PSROP Study Variables

Three types of study data—(1) patient characteristics (eg, age, sex, race, payer, type of stroke, side of stroke, admission severity of illness, functional status measures), (2) process variables (eg, treatments, interventions), and (3) outcome variables (eg, discharge functional status, discharge severity of illness, discharge destination)—were obtained from multiple sources either at the point of care or from postdischarge chart review in the IRF.

PSROP Data Collection

Point-of-care data. The study's physicians, nurses, psychologists, social workers, and physical, occupational, recreational, and speech language pathology therapists each created a form to include the level of intervention intensity they thought was needed to capture a complete and accurate picture of the contribution made by that discipline to rehabilitation care (beyond what was already contained in traditional medical record documentation). Each rehabilitation discipline developed its own content and decided on the frequency with which its form should be completed. One therapy intervention documentation form was completed for each patient treatment session. Examples of forms used by physical therapists, occupational therapists, and speech-language pathologists are given elsewhere.[33]

Disease-specific severity-of-illness data (signs and symptoms). The Comprehensive Severity Index (CSI) is the study's principal severity adjuster. The CSI is an exhaustive, disease-specific severity system that provides a consistent method of defining severity of illness levels using over 2200 individual patient historical factors, physiologic parameters, laboratory results, and physical findings. In the CSI, severity is defined as the physiologic and psychosocial complexity presented to medical personnel due to the extent and interactions of a patient's disease(s).[33] The CSI was measured separately for admission to rehabilitation (first 24h), discharge from rehabilitation (discharge day), and maximum. (Maximum CSI covers the full rehabilitation stay, including admission and discharge period.) Often a patient is the sickest on admission, and thus the admission and maximum CSI scores will be the same. However, when iatrogenic conditions develop, the maximum CSI score becomes larger (more severe) than the admission score. Discharge CSI scores typically are the lowest, because patients have improved and stabilized throughout the rehabilitation stay.

Additional patient, process, and outcome data. In addition to disease-specific severity-of-illness information, the CSI software system allows for the collection of additional study-specific patient, process, and outcome data elements, identified and defined by the project clinical team into an instrument called the auxiliary data module (ADM). Most variables contain date and time fields so that they can be associated with other variables in time sequence. The PSROP ADM contained over 200 variables, many of which have numerous data entries. For example, some data related to vital signs, weight, and pain, among others, were collected for each day of the rehabilitation stay, so these single variables have as many entries as the length of stay (LOS). Outcome variables in the ADM included discharge FIM instrument scores, LOS, death, and discharge destination. Patient and process variables included living situation, ambulation, activities of daily living (ADLs), and employment before stroke; age; sex; payer source; admission FIM score; case-mix group (CMG) (used for Medicare payment purposes); rehabilitation LOS; and acute admission LOS.[33]

The functional performance for each study patient on admission to and discharge from inpatient rehabilitation was obtained via retrospective chart review using the study site's reporting of FIM scores. We assumed all clinicians providing FIM data within IRFs, as part of standard practice, were FIM credentialed; no additional documentation of FIM elements was performed for project purposes. We assigned each study patient to a CMG following stroke CMG definition rules based on motor FIM score, cognitive FIM score, and patient age.[33,35,36]

Patient sample. From the 1161 PSROP patients, we excluded patients who died and outlier patients admitted to rehabilitation more than 200 days after stroke symptom onset. There were 1031 patients remaining for study from the 6 U.S. rehabilitation sites.

Preliminary analyses showed that admission CMG was a stronger predictor of functional outcome than admission FIM score alone. Therefore, we chose to analyze the 1031 patients within CMG groupings while controlling for admission FIM scores as independent variables in regression analyses. To maintain sample sizes large enough to detect small effect sizes, CMGs were combined into moderate (CMGs 104–107, n=486 patients) and severe (CMGs 108–114, n=483 patients) patient groups. We focused analyses on the 969 patients with moderate and severe stroke, because there were too few patients with mild stroke in CMGs 101 to 103 (n=62).

Processes and Interventions

Timing of rehabilitation after stroke. To determine the relation between days from onset of stroke symptoms to rehabilitation admission and functional outcomes, we defined the following variable: number of days from stroke onset (defined as first symptom onset) to admission to a dedicated rehabilitation unit. Other time intervals were defined as control variables. For example, days from symptom onset to acute care hospital admission was included in the regression models. In some cases, a patient experienced the onset of stroke symptoms during an acute care hospital stay (eg, for a cardiac procedure), yielding a negative number of days from symptom onset to acute care admission. In these cases, we counted the number of days from symptom onset to acute care hospital admission as zero. Similarly, if a patient was receiving therapy in the hospital before onset of stroke symptoms, the number of days between symptom onset and initiation of therapy was counted as zero.

Outcomes

FIM subscores. The FIM provides a useful global measure of functional independence. However, we found that patients with identical FIM scores actually differed markedly in distinct aspects of functioning that are targeted by particular therapies. Therefore, we used FIM subscores indicating impairment in specific domains—such as ADLs, motor function, or mobility—as outcome measures. To obtain the FIM ADL subscore, 6 individual FIM component scores for activities (bathing, eating, grooming, dressing upper body, dressing lower body, toileting) were added. To obtain the FIM mobility subscore, 3 individual FIM component scores for transfers (toilet; bed, chair, and wheelchair; tub and shower transfers) and 2 individual FIM component scores for locomotion (stairs, walk and wheelchair locomotion) were added together. The FIM motor subscore was the sum of the FIM mobility subscore, the FIM ADL subscore, and the FIM component scores for bladder and bowel control.

Statistical Methods

Ordinary least squares regression was used to examine associations between days from symptom onset to rehabilitation admission with each resident functional outcome at discharge, controlling for age, sex, race, ambulation independence before admission, ADL independence before admission, rehabilitation LOS, side of brain affected by stroke, days from symptom onset to acute care admission of 4 or more, acute care LOS of 20 days or more, and admission to IRF after implementation of a new prospective payment system.

All potential predictor variables were checked for multicollinearity; no correlations were greater than .50. Stepwise R^2 selection procedure allowed independent variables to enter and leave each model. The importance of each predictor was determined by its F value. We created the most parsimonious model for each outcome by allowing only significant ($P<.05$) variables to remain in the model. Analyses were performed within subpopulations (CMG groups) of the sample. All analyses were performed with SAS statistical software.[a]

RESULTS

Descriptive Statistics

Characteristics of the 969-patient sample (age, sex, race, payer, stroke characteristics, FIM scores and subscores, severity-of-illness scores, number of days from stroke onset to rehabilitation admission) are shown in table 1. In addition, rehabilitation LOS, discharge destination, and other functional and severity outcome data are presented for the 969-patient sample.

Days From Stroke Symptom Onset to Rehabilitation Admission

We hypothesized that delayed time to rehabilitation admission would be associated with lower functional outcomes, as measured by FIM scores (or subscores) at discharge from rehabilitation. First, we examined the association of days from symptom onset to rehabilitation admission alone as a predictor of discharge outcomes in simple ordinary least squares regression analyses. These findings are presented in table 2. In both groups (CMGs 104–107, 108–114), more days from stroke symptom onset to rehabilitation admission was associated significantly with lower discharge total FIM, discharge motor FIM, discharge mobility FIM, and discharge ADL FIM scores. In moderately impaired patients (CMGs 104–107), days from stroke symptom onset to rehabilitation admission had a P value of .042 or less for all FIM subscores, and in severely impaired patients (CMGs 108–114), days from stroke symptom onset to rehabilitation admission had a P value of .008 or less for all FIM subscores. In the moderately impaired group, more days from stroke onset to rehabilitation admission also was associated significantly with longer rehabilitation LOS ($P<.001$). By comparison, the severely impaired group did not show an association between days from symptom onset to rehabilitation admission with LOS ($P=.39$).

Next we performed multiple regression analyses, allowing many additional patient and treatment characteristics to enter the models for the various discharge outcome variables. The findings are presented in tables 3 and 4. In table 3 we examine patients with moderate stroke in CMGs 104 to 107. When many additional patient (including maximum CSI) and treatment variables were allowed to enter the model, we found that days from stroke onset to rehabilitation admission remained statistically significant and in the same directions as in the single-variable regression analyses. In table 4, we examine patients with severe stroke in CMGs 108 to 114. Again, the findings from table 2 remain when many additional patient (including maximum CSI) and treatment variables were allowed to enter the models. Patient and treatment variables that entered significantly in each of these equations were in the expected directions related to the outcomes.

DISCUSSION

The purpose of the multicenter PSROP was to open the "black box" of rehabilitation and determine, as precisely as possible, how specific elements of the rehabilitation process contribute to clinical outcomes. Timing of initiation of rehabilitation is one of those elements. Consistently, we found that fewer days from onset of stroke symptoms to rehabilitation admission was associated significantly with better functional

Table 1: Study Sample Patient, Process, and Outcome Characteristics

PSROP Variables	N*	Value
Patient Characteristics		
Mean age (y)	969	66.6±14.4
Sex (% male)	969	52.0
Race (%)	969	
White		54.9
Black		25.7
Other, including Hispanic		19.4
Payer (%)	969	
Medicare		58.4
Medicaid		10.6
Commercial		27.7
Self-pay		2.6
Unknown/missing		0.7
Type of stroke (%)	969	
Hemorrhagic		24.5
Ischemic		75.5
Side of stroke (%)	969	
Right		44.3
Left		43.1
Bilateral		9.9
Unknown		2.7
Mean admission total FIM score	969	57.8±18.3
Mean admission motor FIM score	969	37.4±12.3
Mean admission cognitive FIM score	969	20.5±8.3
CMG (%)	969	
Moderate (104–107)		50.2
Severe (108–114)		49.8
Mean rehab admission CSI score	969	21.6±14.0
Mean no. of days from stroke onset to rehab admission	958	13.8±18.7
Process variables		
Mean LOS	969	19.6±10.1
Outcome variables		
Mean maximum CSI score	969	32.3±20.9
Increase in severity (maximum − admission CSI scores)	969	10.7±11.2
Mean discharge CSI score	969	10.5±11.9
Mean gross medical improvement (maximum − discharge CSI scores)	969	21.7±15.0
Mean net medical improvement (admission − discharge CSI scores)	969	11.1±9.9
Mean discharge total FIM score	955	85.2±21.9
Mean increase in total FIM score (discharge − admission)	955	27.3±14.1
Mean discharge motor FIM score	958	60.2±16.8
Mean increase in motor FIM score (discharge − admission)	958	22.8±11.9
Mean discharge cognitive FIM score	964	24.9±7.5
Mean increase in cognitive FIM score (discharge − admission)	964	4.4±4.2
Discharge destination (%)	969	
Community discharge including home		80.1
Home only		76.8
Inpatient institutional discharge		19.9

NOTE. Values are mean ± standard deviation or as otherwise indicated.
Abbreviation: rehab, rehabilitation.
*One site did not use the speech and language pathology intervention documentation forms. Data from the other 5 sites are included here.

outcomes: higher total, motor, mobility, and ADL discharge FIM scores. For severely impaired patients with stroke in CMGs 108 to 114, the relation was strongest, with F statistics greater than 24.1 for each functional outcome.

Also, for patients with moderately severe stroke in CMGs 104 to 107, fewer days from onset of stroke symptoms to rehabilitation admission was associated significantly with a shorter rehabilitation LOS ($P=.038$). The most intuitive reason for this relation is that those patients with less severe strokes and/or medical comorbidities naturally would be able to begin rehabilitation sooner and would also progress faster through rehabilitation, resulting in a shorter LOS. However, this relation was true after controlling for medical comorbidity and complications with the maximum CSI score. Perhaps earlier rehabilitation efforts provide patients with more practice opportunities to maximize functional gains, giving them a head start on entering rehabilitation. Or it could be that the additional stimulation of early rehabilitation enhances blood flow to injured areas and/or the ischemic penumbra, speeding clearance of toxic waste products such as free radicals and enhancing the healing process rather than inhibiting it. The optimal time window for increased synaptic plasticity (as mentioned elsewhere) may also occur early in the poststroke period, allowing for greater gains if rehabilitation is carried out during this critical interval. Additional research in laboratory animals could be done to confirm or refute this hypothesis, but the generalizability of the results in humans would still be uncertain.

Having microlevel data provided the ability to focus on the individual patient level to explore reasons for our findings and whether the findings would disappear when other variables were controlled for. The CSI enabled us to go beyond controlling only for stroke severity: it allowed us to control for many complex comorbidities common to patients with stroke, reflecting more accurately the realities of clinical practice. The maximum CSI score predicted outcomes as expected: a higher

Table 2: Days From Stoke Onset to Rehabilitation Admission: Associations With Discharge FIM Scores and Rehabilitation LOSs*

	Days From Stroke Onset to Rehabilitation Admission as a Single Independent Variable		
Outcome Variable	Coefficient†	*P*	R^{2}‡
Moderate Stroke (CMGs 104–107)			
Discharge total FIM score	−.17	<.001	.025
Discharge motor FIM score	−.12	.001	.023
Discharge mobility FIM score	−.07	<.001	.038
Discharge ADL FIM score	−.04	.042	.009
Rehab LOS	.09	<.001	.024
Severe Stroke (CMGs 108–114)			
Discharge total FIM score	−.11	.008	.015
Discharge motor FIM score	−.10	.003	.019
Discharge mobility FIM score	−.04	<.001	.024
Discharge ADL FIM score	−.05	.001	.022
Rehab LOS	.02	.394	.002

*For CMGs 104–107, n=475; for CMGs 108–114, n=469.
†For simple ordinary least squares regression, "+" represents more days from onset to rehabilitation associated with longer rehabilitation LOS and "−" represents more days from onset to rehabilitation associated with lower discharge FIM subscores.
‡The proportion of variation in a specified outcome explained by predictor variables.

Table 3: Regression Results for Outcomes of Discharge FIM Scores and Rehabilitation LOS for Patients With Moderate Stroke in CMGs 104 to 107 (n=475)

	Dependent Variables											
	Discharge Total FIM Score			Discharge Motor FIM Score			Discharge Mobility FIM Score			Rehabilitation LOS (n=480)		
Independent Variables	Coeff	F	P	Coeff	F	P	Coeff	F	P	Coeff	F	P
Days from stroke onset to rehab admission	−0.11	8.2	.004	−0.12	11.7	<.001	−0.08	24.8	<0.001	0.05	4.3	.038
Partial R^2		.010			.013			.030			.01	
Age	−0.13	14.4	<.001	−0.12	16.4	<.001	−0.05	15.1	<.001			
Female							−0.69	3.9	.050			
Admission motor FIM score	0.56	44.7	<.001	0.55	55.8	<.001	0.23	44.7	<.001	−0.33	36.6	<.001
Admission cognitive FIM score	0.70	105.4	<.001				−0.07	6.5	.011	−0.09	4.2	.042
Maximum CSI score	−0.12	11.7	<.001	−0.07	5.2	.023				0.09	16.8	<.001
Employed PTA	3.91	12.2	<.001	2.57	7.1	.008	1.10	5.7	.017	1.66	5.9	.015
Ambulate Independently PTA				2.25	4.3	.039	1.02	3.9	.049	1.67	3.8	.050
R^2		.413			.279			.275			.191	

NOTE. Variables allowed in regressions; age, female, admission motor FIM score, admission cognitive FIM score, ambulation independent before admission, ADLs independent before admission, employed before admission, maximum severity score (CSI), rehab LOS, stroke on right side of brain, stroke on left side of brain, bilateral stroke, stroke on unknown side of brain, race, days from symptom onset to acute admission ≥4, acute admission LOS ≥20 days, post PPS.
Abbreviations: Coeff, coefficient; PPS, prospective payment system; PTA, prior to admission.

score (sicker patient) was associated with a lower discharge FIM score and its component scores and also with a longer rehabilitation LOS. These data support the hypothesis that early inpatient rehabilitation for patients with moderate and severe stroke and more days of acute inpatient rehabilitation for patients with severely impaired stroke are associated with better functional outcomes, after controlling for severity of illness. The findings also are consistent with prior literature regarding the importance of such variables as age, sex, race, severity of illness, baseline level of function, and employment before stroke.

It should be noted that the standard deviation of the time interval from stroke onset to initiation of rehabilitation was quite large (see table 1). This variability is at least in part due

Table 4: Regression Results for Outcomes of Discharge FIM Scores and Rehabilitation LOS for Patients With Severe Stroke in CMGs 108 to 114 (n=469)

	Dependent Variables Score														
	Discharge Total FIM Score			Discharge Motor FIM Score			Discharge Mobility FIM Score			Discharge ADL FIM Score			Rehab LOS (n=478)		
Independent Variables	Coeff	F	P	Coeff	F	P	Coeff	F	P	Coeff	F	P	Coeff	F	P
Days stroke onset to rehab adm	−0.15	26.7	<.001	−0.14	28.2	<.001	−0.05	24.1	<.001	−0.06	24.5	<.001			
Partial R^2		.022			.027			.032			.024				
Age	−0.22	15.3	<.001	−0.20	16.5	<.001	−0.08	14.1	<.001	−0.07	9.5	.002	−0.13	14.0	<.001
Black	−3.75	5.1	.024	−2.85	4.2	.041									
Stroke on right side of brain				−2.36	4.0	.046	−1.22	5.6	.018						
Stroke on left side of brain										1.47	6.8	.009			
Admission motor FIM score	1.22	104.0	<.001	1.18	157.0	<.001	0.44	143.8	<.001	0.47	101.4	<.001	−0.32	18.0	<.001
Admission cognitive FIM score	0.86	63.9	<.001							0.10	5.8	.017	0.14	4.0	.046
Maximum CSI score	−0.16	18.0	<.001	−0.12	17.6	<.001				−0.06	18.7	<.001	0.11	21.9	<.001
Employed PTA	4.87	7.0	.008	4.33	7.8	.006	1.41	4.3	.039	1.79	6.2	.013	2.40	4.2	.042
ADLs independent PTA				3.77	4.5	.034	1.69	4.8	.029				4.91	14.0	<.001
Rehab LOS	0.45	39.6	<.001	0.30	23.9	<.001	0.08	9.1	.003	0.16	32.3	<.001			
Post PPS													−1.91	4.1	.043
R^2		.540			.443			.322			.428			.197	

NOTE. Variables allowed in regressions: age, female, admission motor FIM, admission cognitive FIM, ambulation independent prior to admission, ADLs independent prior to admission, employed prior to admission, maximum severity score (CSI), rehab LOS, stroke on right side of brain, stroke on left side of brain, bilateral stroke, stroke on unknown side of brain, race, days from symptom onset to acute admission ≥4, acute admission LOS ≥20 days, post PPS.
Abbreviation: adm, admission.

to the wide range of practices in delivery of poststroke rehabilitation care that exist between different regions of the country, hospital systems, and provider groups. In some areas, patients sometimes were discharged to skilled nursing facilities before entering inpatient rehabilitation. Hospital bed availability, staffing shortages, insurance coverage, and socioeconomic status of patients all potentially contribute to the variation in the time interval between stroke onset and rehabilitation. Efforts to reduce this variability by prioritizing timely rehabilitation of patients with stroke could result in substantial improvements in patient functional status, reduced LOS, and decreased health care costs.

As mentioned earlier, some have theorized that early aggressive rehabilitation potentially might be harmful to patients with stroke because of increased oxidative and/or metabolic stress on vulnerable cells. It is of interest, therefore, that the most severely impaired group had the strongest association between earlier rehabilitation and better functional outcomes. Presumably, if this theory were true, these severely affected patients would be most vulnerable to any harmful effects of early rehabilitation. In fact, it is this group that apparently gains the most functional benefits from early rehabilitation. These results concur with our findings in subgroup analyses of physical therapy, occupational therapy, and speech-language pathology therapy.[37-39]

This is encouraging news. Although the evidence is not conclusive, the findings from this multicenter study regarding timing of initiation of rehabilitation after stroke suggest that we need not fear implementing early, aggressive interventions for severely affected patients with stroke; on the contrary, it appears to be the best thing we can do to maximize return of function. In addition, moderately affected patients with stroke apparently benefit from early rehabilitation, both in terms of functional outcomes and shorter LOS. Hence, greater efforts to initiate rehabilitation as soon as feasible and to transfer patients to dedicated rehabilitation facilities in a timely manner should result in greater rehabilitation efficiency and improved functional outcomes in most patients with stroke. Lack of a defined time point for measurement of functioning after stroke was a limitation of the study. Ideally, the FIM score would be measured at some predetermined endpoint (eg, 30d after stroke onset) for all patients. Use of rehabilitation discharge FIM scores is less satisfactory, because discharge itself is affected by institutional policies, patient preferences, socioeconomic concerns, insurance coverage, rate of recovery, and other variables. Despite these limitations, these analyses offer opportunities to uncover new insights and to confirm or reject original hypotheses. The significance of the time period between stroke onset and rehabilitation admission provides opportunities to alter care processes to achieve best possible outcomes.

As the population ages and the health care system faces challenges of providing high quality care with limited resources, it is increasingly important to identify the most effective and efficient means of delivering rehabilitation services to patients with stroke. There are enormous challenges inherent in studying a topic as complex as stroke rehabilitation. Strokes and patients with stroke are heterogeneous. Rehabilitation interventions vary in content, process, duration, intensity, and purpose. Functional outcome measures are difficult to define and interpret. The CPI methodology applied in this project enabled a comprehensive and detailed approach to this topic. The findings provide evidence for the importance of early rehabilitation in patients with stroke routinely encountered in clinical practice, and they could help lay the groundwork for future research and possibly randomized controlled trials.

CONCLUSIONS

For moderately and severely impaired patients with stroke, fewer days between onset of stroke symptoms and admission to inpatient rehabilitation is associated with better functional outcomes at discharge. For moderately impaired patients with stroke, fewer days between onset of stroke symptoms and admission to acute inpatient rehabilitation also is associated with shorter rehabilitation LOS. Providers should strive to transfer patients with stroke as soon as possible from an acute care hospital into acute rehabilitation to improve functional outcomes.

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ORIGINAL ARTICLE

Physical Therapy During Stroke Rehabilitation for People With Different Walking Abilities

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ABSTRACT. Latham NK, Jette DU, Slavin M, Richards LG, Procino A, Smout RJ, Horn SD. Physical therapy during stroke rehabilitation for people with different walking abilities. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S41-50.

Objective: To describe how physical therapy (PT) activities during poststroke inpatient rehabilitation vary by admission walking ability and over time.

Design: Observational cohort study.

Setting: Six inpatient rehabilitation hospitals in the United States.

Participants: People receiving poststroke PT (N=715) who were classified as walking at admission.

Interventions: Not applicable.

Main Outcome Measures: Percentage of time spent in 11 activities, percentage of patients who participated in each activity, and the FIM instrument scores.

Results: The majority of PT time was spent in gait activities. Even people with the most limited mobility spent 25% to 38% of PT time in gait activities during the first 6-hour treatment block. Treatment progression was evident, and a shift to more advanced activities occurred over time (eg, less bed mobility and more advanced gait). However, even in the final 6-hour block, a small proportion of time was spent on community mobility activities (1.2%–5.2%), and most people received no community mobility training.

Conclusions: PT activities focused on specific functional tasks at the ability level of each individual patient and provided higher-level activities as patients improved their function. However, although there is increasing recognition that the environment influences task performance, little time was spent in community mobility activities before discharge.

Key Words: Clinical practice patterns; Physical therapy; Rehabilitation; Stroke; Walking.

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PHYSICAL THERAPY (PT) is a standard part of rehabilitation after a stroke in most countries, with numerous guidelines recommending that all stroke patients receive PT.[1,2] However, the literature contains few studies that describe precise activities that physical therapists provide to people after a stroke. Recent systematic reviews have provided comparisons of different PT approaches to stroke rehabilitation, but the trials included in the reviews rarely provide specific details about all PT activities used throughout the course of rehabilitation.[3,4]

Some observational studies have explored PT treatment poststroke. A few studies have described how patients spend their time during inpatient stroke rehabilitation, but they have focused more broadly on whether patients were alone or active[5] or have described PT treatment only in terms of duration or frequency of therapy.[6,7] Most studies have involved a limited number of patients[7-9] or have asked therapists about treatment choices for hypothetical patients.[10] A recent study by Bode et al[11] provides among the most comprehensive assessments to date of the pattern of rehabilitation activities during inpatient stroke rehabilitation. However, this study only reported activities that were classified into 2 general categories: function or impairment activities.[11] None of the studies identified examined how specific PT treatments change over time during the course of stroke rehabilitation or by patients' functional statuses.

Without data to describe reliably poststroke PT activities, it is not known whether current practice follows treatment approaches described in the stroke rehabilitation literature. Many recent review articles, textbooks, and stroke guidelines have emphasized a task-oriented approach to therapy.[2,4,12-16] This approach emphasizes practice of identifiable functional tasks, rather than movement patterns for movement's sake alone.[16] This approach to training has several key features. Although there is still a need to address the underlying impairments, the main focus of this training is on specific tasks.[15,16] When task-specific training is occurring, there should be individualization of the training goals (ie, tasks must be at the appropriate level for a patient's ability) and progression of the training goals over time (ie, as the patient improves, tasks should become progressively more challenging).[15] Finally, it is well established that the environmental context of the training influences performance of the task. Therefore, to retrain functional adaptation, it is important that activities are carried out in different settings, including in settings that provide environmental challenges that are similar to those that a patient will experience on return to his/her community.[16] By examining PT activities over the duration of rehabilitation and among patients with different abilities to walk, the incorporation of these principles into current practice can be explored.

This work is part of the Post-Stroke Rehabilitation Outcomes Project (PSROP). A detailed literature review substantiating the need to examine rehabilitation processes to improve outcomes for specific types of patients is presented elsewhere.[17] Also described elsewhere is an introduction on where clinical practice improvement methods fit into the pantheon of biomedical and clinical research methodology.[18] This study builds on

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Table 1: Patient Characteristics, Processes, and Outcome Variables by Amount of PT Received

PSROP Variable	No. of 6-Hour Blocks of PT			
	1 (n=277)	2 (n=233)	3 (n=135)	4 (n=70)
Patient Characteristics				
Mean age (y)	67.1	67.7	66.2	61.1
Race (%)				
White	57.0	56.2	57.8	58.6
Black	23.8	27.5	30.4	30.0
Other, including Hispanic	19.1	16.3	11.9	11.4
Sex (% men)	48.4	49.4	58.5	51.4
Type of stroke (%)				
Hemorrhagic	26.0	20.6	20.0	20.0
Ischemic	74.0	79.4	80.0	80.0
Side of stroke (%)				
Left	42.2	41.6	43.0	41.4
Right	43.7	45.5	44.4	47.1
Bilateral	10.8	10.3	9.6	8.6
Unknown	3.2	2.6	3.0	2.9
Mean admission motor FIM score	46.8	39.5	35.7	31.5
Mean admission cognitive FIM score	22.6	21.3	20.5	19.3
Mean days from onset to rehab admission	10.3	14.0	17.6	16.7
Process variables				
Mean length of stay	12.2	18.3	24.0	31.4
Mean total minutes of PT	471.0	818.6	1157.0	1518.0
Mean total no. of PT sessions	12.1	22.7	30.5	35.6
Outcome variables				
Discharge destination (%)				
Home	83.4	80.7	78.5	85.7
Board and care (assisted living)	1.1	4.7	4.4	2.9
Skilled nursing facility	11.2	11.6	14.1	8.6
Acute hospital (own or other facility)	2.9	1.3	2.2	2.9
Other rehabilitation facility	1.4	1.7	0.7	0.0
Mean discharge motor FIM score (95% CI)	68.2 (66.5–70.0)	64.2 (62.2–66.2)	59.5 (57.0–62.0)	58.5 (55.4–61.6)
Mean discharge cognitive FIM score (95% CI)	26.1 (25.3–27.0)	25.9 (25.0–26.8)	25.4 (24.2–26.7)	25.4 (23.8–27.0)

Abbreviations: CI, confidence interval; rehab, rehabilitation.

earlier work that described the overall treatment activities provided by physical therapists for PSROP patients[19] by exploring how these treatments vary over the duration of inpatient rehabilitation and according to the patients' mobility limitations. We also explored in one example how these data could be used to describe activities associated with mobility outcomes in a very specific and homogeneous group of patients.

METHODS

The methodology governing the full PSROP, provided in this supplement by Gassaway et al,[20] provides a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, and a detailed description of the project's final study group. The methodology is summarized in Maulden et al.[21] The institutional review boards at Boston University and at each participating inpatient rehabilitation facility (IRF) approved the study.

Patients in PT Subset

For analyses reported in this article, patients who had fewer than 5 hours of PT during their rehabilitation (n=119) and those who had had more than 30 hours of therapy (n=49) were excluded. These exclusions were made based on our data showing that patients in these groups may have had important differences in illness severity and function from the group receiving 5 to 30 hours of therapy. Additionally, patients were excluded if they were classified as using a wheelchair for locomotion on admission. Data analyses in this article are, therefore, based on 715 patients who received between 5 and 30 hours of PT during their rehabilitation stay and were classified as walking at admission, regardless of the level of independence in walking. Demographic data describing the patients are included in table 1.

Instrumentation

The PT intervention documentation form (appendix 1) developed for the PSROP included a taxonomy of information such as targeted activity area, interventions used by the clinician within each activity, and duration of each activity measured in 5-minute increments.[22] Definitions for the activities and interventions contained on the PT intervention documentation form were provided to practicing clinicians and are available on request. One PT intervention documentation form was completed for each PT session a patient received during his/her inpatient rehabilitation stay.

A lead physical therapist from each IRF participated in a train-the-trainer teleconference to learn how to use and teach others to use the PT intervention documentation form. After the teleconference, the lead physical therapists trained colleagues in their respective IRFs.

Each site incorporated auditing of intervention documentation form use into routine site practices. Typically, the lead physical therapist observed a patient session and completed a separate intervention documentation form based on what was observed. The therapist providing the session completed a form as per protocol. The lead therapist reviewed and discussed differences in completion with the practicing therapist.

Face validity was built into the intervention documentation forms because they were developed and used by IRF therapists as described above. Predictive validity was assessed by showing significant effects of PT interventions (and other therapy interventions) on outcomes.[23-25] For example, the amount of variation explained in discharge FIM score, controlling for patient characteristics (including admission FIM score, severity of illness, demographic factors), was 40% for moderate strokes and 45% for severe strokes. When total time per day spent on PT, occupational therapy (OT), and speech-language pathology (SLP) was added, there was no increase in variation explained for discharge FIM, consistent with previous findings by Bode et al.[11] However, when time per day spent in specific PT, OT, and SLP activities was added, the amount of variation explained increased to 52% for moderate strokes and 68% for severe strokes, adding 12% to 23% explanation of variation, respectively, in discharge FIM score.

Functional performance for each study patient at admission to and discharge from inpatient rehabilitation was obtained via retrospective chart review using each study site's reporting of the FIM scores.[1,26] We assumed all clinicians providing FIM data within IRFs as part of standard practice were FIM credentialed; no additional documentation of FIM elements was performed for project purposes.

Data Analysis

Patients were categorized by 2 factors, their functional ability at admission to rehabilitation and the duration of their PT treatment. Patients were first classified accordiug to their functional ability based on their admission score on the FIM locomotion item (description in appendix 2). We created 2 functioual groups: (1) score of 1 or 2 on the locomotion FIM item (severe limitation in locomotion) and (2) score of 3 or better on the locomotion FIM item (moderate or less limitation in mobility).

Patients were then categorized based on the duration of PT services. Four categories of patients were created: those who received 1, 2, 3, and 4 six-hour blocks of PT across their episode of care. Because data concerniug activities were collected across an entire session and because PT sessions differed in length, each 6-hour block of therapy for patients could contain a variable number of sessions. We, therefore, classified patients using the number of full sessions that would bring the therapy hours the closest to 6, 12, 18, or 24 without including the next time block. For example, patients classified as having 1 six-hour block of therapy received between 5 and 11 hours of PT during their rehabilitation stay with an average total time of 471.0 minutes (95% confidence interval, 458.0–483.9). We examined the content of PT sessions, however, for only the first 6 hours.

Descriptive statistics were derived to examine characteristics of patients within each category, as well as characteristics of their episodes of care. The content of treatment sessions was described first by determining the percentage of all PT time within each 6-hour block spent on examination and evaluation. Examination and evaluation time then was subtracted from total therapy time, and percentage of the remaining time spent in each activity was determined.

Finally, we selected a specific subset of patients to explore a method to refine the description of PT sessions and to describe the association between activities and outcome based on the FIM locomotion item. Based on our earlier descriptive data, we selected patients who received 3 six-hour blocks of PT and who had an admission FIM locomotion score of 1 (totally dependent) to create a somewhat homogeneous group of patients. This group of patients was then further stratified according to their discharge scores on the FIM locomotion item: less than 4 or greater than or equal to 4. The PT sessions for these groups of patients were described in terms of the percentage of time spent in each activity during the first 3 hours of therapy. Three hours was chosen for this analysis because we expected only minimal to moderate effects of natural recovery during that time period, and we wished to minimize the effect of improvements in patients' physical functioning on selection of activities.

RESULTS

The average percentage of time spent in each activity for patients receiving 1, 2, 3, and 4 six-hour blocks of therapy can be found in tables 2 through 5.

Table 2: Characteristics of PT Sessions for Patients With 1 Six-Hour Block of PT

Activity*	% Patients†	Mean % Time‡ (95% CI)
Admission locomotion 1 or 2 (n=174)		
Prefunctional	87.9	19.2 (17.2–21.2)
Bed mobility	58.0	4.3 (3.4–5.2)
Sitting	40.2	3.3 (2.4–4.2)
Transfers	86.2	10.5 (9.3–11.7)
Sit to stand	75.3	6.8 (5.8–7.8)
Wheelchair	40.8	2.1 (1.6–2.6)
Pregait	68.4	7.4 (6.2–8.6)
Gait	97.7	37.9 (35.5–40.3)
Advanced gait	59.2	6.4 (5.2–7.7)
Community mobility	17.8	1.9 (0.9–2.8)
Using cane	41.4	NA
Using ankle-foot orthosis	14.4	NA
Admission locomotion ≥3 (n=103)		
Prefunctional	91.3	21.2 (18.4–23.9)
Bed mobility	25.2	1.0 (0.6–1.5)
Sitting	22.3	1.3 (0.7–1.8)
Transfers	64.1	5.4 (4.0–6.8)
Sit to stand	53.4	3.7 (2.8–4.7)
Wheelchair	13.6	0.6 (0.3–1.0)
Pregait	68.0	8.1 (6.2–10.0)
Gait	100.0	42.6 (39.6–45.6)
Advanced gait	75.7	11.5 (9.2–13.9)
Community mobility	28.2	4.0 (2.3–5.6)
Using cane	58.3	NA
Using ankle-foot orthosis	9.7	NA

Abbreviation: NA, not applicable.
*Activities reported as percentage of time spent outside of examination and evaluation during the block.
†Percentage of patients receiving this activity during the 6-hour block.
‡Mean percentage of total time across patients spent in the activity during the 6-hour block.

Table 3: Characteristics of PT Sessions for Patients With 2 Six-Hour Blocks of PT

Activity*	1 Block		2 Blocks	
	% Patients†	Mean % Time‡ (95% CI)	% Patients†	Mean % Time‡ (95% CI)
Admission locomotion 1 or 2 (n=202)				
Prefunctional	91.1	20.8 (18.8–22.8)	93.1	23.4 (21.3–25.5)
Bed mobility	58.9	4.2 (3.4–4.9)	42.1	2.8 (2.1–3.4)
Sitting	42.6	4.2 (3.1–5.2)	32.7	3.1 (2.1–4.0)
Transfers	86.1	11.8 (10.5–13.1)	80.7	8.5 (7.3–9.8)
Sit to stand	76.7	7.6 (6.6–8.6)	61.4	5.1 (4.3–6.0)
Wheelchair	44.6	2.2 (1.7–2.7)	32.2	1.5 (1.1–2.0)
Pregait	79.7	9.9 (8.6–11.2)	72.3	7.0 (5.9–8.1)
Gait	95.0	35.9 (33.5–38.3)	96.0	38.1 (35.6–40.6)
Advanced gait	39.1	2.8 (2.1–3.5)	57.9	7.2 (6.0–8.4)
Community mobility	6.9	0.5 (0.2–0.7)	23.8	2.9 (1.8–4.1)
Using cane	56.9	NA	61.4	NA
Using ankle-foot orthosis	29.7	NA	100.0	NA
Admission locomotion ≥3 (n=31)				
Prefunctional	90.3	23.0 (17.5–28.6)	93.5	27.0 (20.4–33.7)
Bed mobility	45.2	3.0 (0.8–5.2)	25.8	1.2 (0.2–2.2)
Sitting	32.3	1.6 (0.4–2.9)	19.4	1.7 (−0.1 to 3.5)
Transfers	77.4	7.0 (4.4–9.6)	58.1	4.2 (2.4–6.0)
Sit to stand	61.3	4.4 (1.9–7.0)	41.9	3.3 (1.4–5.2)
Wheelchair	22.6	1.1 (0.3–2.0)	12.9	0.9 (−0.4 to 2.1)
Pregait	64.5	7.3 (4.2–10.5)	61.3	4.9 (2.9–7.0)
Gait	100.0	45.0 (38.3–51.7)	100.0	40.8 (34.7–46.9)
Advanced gait	67.7	5.9 (3.5–8.2)	71.0	10.7 (6.8–14.6)
Community mobility	12.9	1.2 (−0.2 to 2.6)	51.6	5.2 (2.5–7.9)
Using cane	58.1	NA	48.4	NA
Using ankle-foot orthosis	12.9	NA	100.0	NA

*Activities reported as percentage of time spent outside of examination and evaluation during the block.
†Percentage of patients receiving this activity during the 6-hour block.
‡Mean percentage of total time across patients spent in the activity during the 6-hour block.

Frequency of Gait Activity

Regardless of the amount of time spent in the rehabilitation setting and the initial level of locomotor function, patients spent most of their time in PT practicing gait. Even during the first 6 hours of PT sessions, patients spent a higher percentage of time in gait than any other activity. That is, approximately 25% to 45% of time was spent in gait activity across groups of patients versus 18% to 20% of time in prefunctional activity (preparation activity related to an upcoming PT activity), the next highest amount of time. During the last 6-hour block of therapy, 96% of patients who began with a FIM locomotion score of 1 or 2 and 100% of patients who began with a FIM locomotion score of 3 or better engaged in gait activity.

PT Activities and Patient Functional Ability

Physical therapists design plans of care for their patients that are aimed at each patient's ability level to perform physical activities. Patients whose admission locomotion FIM scores were 1 or 2 spent as much as 5.6% of their session time in bed mobility, 6.2% of time in sitting activities, and 15.2% of time in transfers during the initial 6-hour block, whereas patients with an admission FIM locomotion score of 3 or better spent 3.0% of their time in bed mobility, 2.9% of time in sitting activity, and 7.0% of time in transfer activities. This pattern was seen in higher-level activities as well. Patients with an initial FIM locomotion score of 1 or 2 spent up to 37.9% of session time in gait activities and 6.4% of session time in advanced gait activities during the initial 6-hour block of therapy, whereas patients with an initial FIM locomotion score of 3 or better spent up to 45% of session time in gait activities and 11.5% of session time in advanced gait activities.

Progression of Plan of Care With Patient Improvement

Physical therapists provide higher-level activities as patients improve in their physical functioning. In patients with more than 1 six-hour block of PT, during the initial 6-hour block of session time patients spent up to 5.6% of their session time in bed mobility and up to 6.2% of their session time in sitting activity. Advanced gait activities comprised up to 5.9% of session time. During the final 6-hour block, when patients might be expected to have improved their physical abilities, patients spent up to 3.5% of their session time in bed mobility and up to 3.1% of their session time in sitting activity. Advanced gait activities comprised up to 10.7% of session time.

Progression to Community Mobility Activities

Time spent in community mobility increased across the time blocks regardless of the admission locomotion function. The percentage of time spent in community mobility during the final 6-hour block of therapy, however, was not greater than 5.2% for any group of patients, and as few as 14.3% of patients (those with admission FIM locomotion scores of 1 or 2 receiving 4 six-hour blocks of therapy) participated in community mobility activities during the final 6-hour block of therapy sessions.

Table 4: Characteristics of PT Sessions for Patients With 3 Six-Hour Blocks of PT

Activity*	1 Block		2 Blocks		3 Blocks	
	% Patients†	Mean % Time‡ (95% CI)	% Patients†	Mean % Time‡ (95% CI)	% Patients†	Mean % Time‡ (95% CI)
Admission locomotion 1 or 2 (n=123)						
Prefunctional	93.5	20.2 (17.9–22.5)	92.7	21.5 (19.0–24.1)	95.9	25.2 (22.3–28.0)
Bed mobility	70.7	5.4 (4.2–6.6)	61.8	4.0 (3.1–5.0)	50.4	3.0 (2.1–4.0)
Sitting	4.0	4.2 (2.9–5.6)	48.0	4.3 (3.1–6.0)	50.4	3.0 (2.1–4.0)
Transfers	95.1	14.1 (12.5–15.7)	89.4	13.1 (11.3–14.9)	85.4	11.5 (9.0–13.9)
Sit to stand	87.0	9.4 (8.1–10.7)	87.8	7.5 (6.5–8.4)	75.6	5.4 (4.2–6.7)
Wheelchair	57.7	3.4 (2.6–4.2)	42.3	2.2 (1.5–2.9)	31.7	2.0 (1.2–2.7)
Pregait	84.6	11.2 (9.6–12.8)	82.9	9.6 (8.0–11.2)	70.7	6.9 (5.7–8.2)
Gait	92.7	29.5 (26.6–32.3)	95.1	36.1 (33.1–39.1)	96.7	38.3 (35.4–41.2)
Advanced gait	17.1	1.1 (0.6–1.6)	34.4	2.8 (1.9–3.7)	96.7	6.5 (5.0–8.0)
Community mobility	6.5	0.6 (0.1–1.0)	8.1	0.5 (0.2–0.8)	19.5	1.7 (0.5–2.9)
Using cane	52.0	NA	65.9	NA	68.3	NA
Using ankle-foot orthosis	43.1	NA	44.7	NA	100.0	NA
Admission locomotion ≥3 (n=12)						
Prefunctional	91.7	23.4 (14.7–32.1)	91.7	21.1 (13.7–28.4)	100.0	31.3 (23.4–39.3)
Bed mobility	41.7	0.9 (0.1–1.6)	8.3	0.2 (−0.3 to 0.8)	25.0	0.6 (−0.2 to 1.4)
Sitting	41.7	2.9 (−1.5 to 7.3)	8.3	1.0 (−1.2 to 3.2)	25.0	0.8 (−0.2 to 1.9)
Transfers	83.3	6.1 (2.9–9.4)	91.7	8.0 (3.9–12.1)	83.3	4.2 (2.1–6.4)
Sit to stand	58.3	3.8 (0.4–7.3)	41.7	2.2 (0.4–4.0)	25.0	0.8 (−0.3 to 1.9)
Wheelchair	50.0	2.1 (0.4–3.9)	8.3	0.1 (−0.1 to 0.4)	25.0	0.7 (−0.2 to 1.5)
Pregait	83.3	14.3 (7.9–20.8)	83.3	6.2 (2.5–10.0)	58.3	4.8 (0.4–9.2)
Gait	100.0	45.0 (34.7–55.3)	100.0	54.3 (45.5–63.2)	100.0	45.2 (35.1–55.2)
Advanced gait	25.0	1.4 (−0.3 to 3.1)	66.7	5.9 (2.0–9.8)	66.7	7.0 (2.4–11.5)
Community mobility	0.0	0.0	16.7	0.9 (−0.6 to 2.5)	66.7	4.6 (2.0–7.1)
Using cane	50.0	NA	58.3	NA	66.7	NA
Using ankle-foot orthosis	25.0	NA	33.3	NA	100.0	NA

*Activities reported as percentage of time spent outside of examination and evaluation during the block.
†Percentage of patients receiving this activity during the 6-hour block.
‡Mean percentage of total time across patients spent in the activity during the 6-hour block.

Outcomes

Patients who had admission FIM locomotion scores of 1 might be considered to be at similar functional levels in terms of walking ability at admission. Based on the notion that plans of care reflect patients' ability levels, one might expect sessions to be somewhat similar in content during the first 3 hours of therapy. However, patients who had FIM locomotion scores of 1 at admission and 4 or greater at discharge spent 32.9% of their PT session time in gait during the first 3 hours of therapy, whereas patients with a FIM locomotion score of 1 at admission and a score less than 4 at discharge spent 12.7% of session time in gait activities (table 6). Similarly, patients with locomotion FIM scores of 4 or greater at discharge spent 7.2% of session time in bed mobility, 5.4% of session time in sitting activities, and 13.8% of session time in transfer activities. Patients with discharge FIM locomotion scores of less than 4 spent 8.9% of session time in bed mobility, 8.6% of session time in sitting activities, and 18.2% of session time in transfer activities.

DISCUSSION

Recent guidelines and reviews recommend that task-specific training be used in PT for people poststroke. However, to date, it has not been possible to determine what specific PT treatment approaches are used in stroke rehabilitation and how therapists adapt their treatments. The PSROP provides among the largest and most detailed explorations of PT in stroke rehabilitation. In general, it appears that the characteristics of PT treatments observed in this study are consistent with the use of a task-based approach in several ways that are outlined below. The 1 area of inconsistency with this approach is the lack of attention to the environmental context of training.

One of the most striking findings of this study is the strong focus that physical therapists have on gait training, which is consistent with the widely accepted principle of specificity of training. This principle has been confirmed in other studies, particular in the trial by Kwakkel et al,[27] which found that therapy focnsed on the lower limb resulted in greater improvements in walking ability whereas therapy focused on the upper limb resulted in improved dexterity, and in a recent systematic review of stroke studies.[6] The current study clearly found that physical therapists spend most of their time on gait retraining. Even among people with the most limited walking ability (ie, admission FIM locomotion score of 1), most were working on gait, and a large proportion of PT time was spent on this activity. The emphasis on gait training also occurs at the very beginning of rehabilitation; this focus is evident in the first treatment block and continues throughout the course of rehabilitation. This finding also is consistent with the work of Bode et al,[11] which found that physical therapists spend most of their time on functional rather then impairment-focused activities.

Despite the strong emphasis on gait training, there was also evidence that therapists used an individualized approach to rehabilitation (ie, the tasks were selected at the appropriate level for a patient's ability). This was seen as patients with higher functional abilities performed more advanced activities, and vice-versa. Again, this finding is consistent with Bode's recent work,[11] which found that physical therapists spent more

Table 5: Characteristics of PT Sessions for Patients With 4 Six-hour Blocks of PT

Activity*	1 Block		2 Blocks		3 Blocks		4 Blocks	
	% Patients†	Mean % Time‡ (95% CI)	% Patients†	Mean % Time‡ (95% CI)	% Patients†	Mean % Time‡ (95% CI)	% Patients†	Mean % Time‡ (95% CI)
Admission locomotion score of 1 or 2 (n=70)								
Prefunctional	90.0	18.4 (15.2–21.7)	84.3	17.1 (13.9–20.4)	88.6	18.3 (14.7–21.8)	88.6	20.6 (17.1–24.0)
Bed mobility	71.4	5.6 (4.3–7.0)	57.1	3.7 (2.6–4.8)	57.1	3.7 (2.4–4.9)	51.4	3.5 (2.1–4.8)
Sitting	57.1	6.2 (4.1–8.3)	45.7	4.0 (2.3–5.7)	37.1	3.1 (1.7–4.6)	32.9	2.3 (1.3–3.2)
Transfers	94.3	15.2 (13.0–17.4)	91.4	12.7 (10.6–14.7)	85.7	10.9 (8.6–13.1)	87.1	13.2 (10.1–16.3)
Sit to stand	87.1	10.2 (8.4–11.9)	84.3	8.9 (7.1–10.7)	82.9	7.9 (6.2–9.6)	77.1	6.4 (4.9–7.8)
Wheelchair	58.6	4.7 (3.1–6.3)	51.4	4.3 (2.8–5.8)	45.7	3.1 (2.1–4.2)	41.4	2.2 (1.3–3.2)
Pregait	91.4	13.1 (10.9–15.4)	87.1	12.7 (10.4–15.1)	81.4	11.2 (8.7–13.7)	78.6	7.8 (5.9–9.7)
Gait	91.4	25.5 (22.1–28.9)	95.7	33.4 (29.6–37.2)	95.7	35.2 (31.2–39.2)	97.1	35.0 (31.3–38.8)
Advanced gait	8.6	0.3 (0.1–0.6)	32.9	2.3 (1.3–3.3)	52.9	4.8 (3.0–6.7)	60.0	7.7 (5.1–10.3)
Community mobility	2.9	0.1 (−0.1 to 0.3)	7.1	0.5 (−0.1 to 1.1)	15.7	1.6 (0.3–3.0)	14.3	1.2 (0.4–2.0)
Using cane	60.0	NA	65.7	NA	67.1	NA	68.6	NA
Using ankle-foot orthosis	47.1	NA	44.3	NA	45.7	NA	100.0	NA

*Activities reported as percentage of time spent outside of examination and evaluation during the block.
†Percentage of patients receiving this activity during the 6-hour block.
‡Mean percentage of total time across patients spent in the activity during the 6-hour block.

time on functional activities with less-impaired people. There was also clear evidence that therapists ensured a progression of training (ie, as the patient improves, tasks become progressively more challenging). An increase in advanced activities such as advanced gait and a decrease in lower-level activities such as bed mobility occurred over time.

One finding of concern was that even in the final week of rehabilitation and in higher-functioning patients, only a small proportion of PT time was spent on community mobility. This study found that across all groups, most people are discharged from stroke rehabilitation with no community mobility training. This was a particularly surprising finding because the vast majority (>80%) of patients were discharged directly to their homes after rehabilitation. The small amount of time devoted to community-based training was not expected, given the growing body of research that indicates that the environment influences the difficulty of mobility tasks.[28,29] The findings about the impact of the environment on task difficulty suggest that people need practice in community environments before they can safely and independently function in that setting. The lack of community mobility preparation also ignores expressed priorities of stroke survivors. In a recent survey, community ambulation was considered to be important or essential by 93% of stroke survivors.[30]

There are many potential reasons why patients might not be receiving community mobility practice. One reason could be the significant reduction in length of stay that has occurred over the past several decades in both acute care and rehabilitation.[31,32] It is possible that a result of reduced time in rehabilitation is that therapists focus on achieving basic daily activities but do not have time to train people in more advanced community-based tasks. Another possible contributor to the focus on more basic activities could be the use of the FIM instrument itself. Rehabilitation hospitals use changes in the FIM as quality indicators of success in rehabilitation. However, the FIM was designed to measure only basic activities of daily living and, as such, does not capture patients' performances in more advanced participation activities.

The lack of community-based preparation before discharge from a rehabilitation hospital places a large burden on home- and outpatient-based services. However, the amount of therapy time that patients receive from these services also is limited and has decreased in recent years.[33] Recent studies found that important declines in function and quality of life occur after discharge from inpatient stroke rehabilitation.[34,35] In particular, Paolucci et al[34] found that mobility declined in over 40% of people on their return home. These findings suggest that in the transition from inpatient rehabilitation to home, a significant number of people experience difficulties. It is possible that a lack of community-based practice before discharge could contribute to some of these problems.

Some limitations of this work include the fact that there were no data available for follow-up after discharge. In addition, the only functional outcome measure is the FIM, a measure of basic activities of daily living. However, the aim of this study was to explore functional changes that take place within inpatient rehabilitation, and this study has numerous strengths in this area. This study included a large number of patients from multiple sites that were geographically distributed around the United States. This increases potential accuracy and generalizability of these findings. Another important feature of this study was the creation of a detailed taxonomy of activities and interventions. This allowed us to have a much more precise understanding of the specific therapeutic treatments that patients received throughout their rehabilitation. Finally, this study involved clinicians from the participating centers during

Table 6: Discharge FIM Locomotion Scores and Percentage of Time Spent in Activities During the First 3 Hours of PT for Patients With 3 Six-Hour Blocks of PT and Admission FIM Locomotion Scores of 1 (n=66)

Activity	Discharge FIM Locomotion Item Score	
	<4	≥4
Prefunctional, mean % time (95% CI)	17.7 (11.2–24.2)	15.4 (10.9–19.8)
Bed mobility, mean % time (95% CI)	8.9 (3.2–14.6)	7.2 (4.3–10.1)
Sitting, mean % time (95% CI)	8.6 (2.9–14.3)	5.4 (2.1–8.8)
Transfer, mean % time (95% CI)	18.2 (14.2–22.2)	13.8 (10.9–16.7)
Sit to stand, mean % time (95% CI)	14.5 (10.3–18.7)	9.6 (6.9–12.2)
Wheelchair, mean % time (95% CI)	5.3 (2.1–8.4)	4.0 (1.3–6.7)
Pregait, mean % time (95% CI)	11.5 (7.4–15.6)	11.1 (7.5–14.7)
Gait, mean % time (95% CI)	12.7 (7.4–15.6)	32.9 (27.3–38.5)
Advanced gait, mean % time (95% CI)	0.0	0.0
Community mobility, mean % time (95% CI)	0.8 (−0.4 to 2.0)	0.0
Using cane (% of patients)	26.9	30.0
Using ankle-foot orthosis (% of patients)	38.5	60.0

all stages of the project. This helped to increase the validity of the study design and integrity of the results.

Additional research questions are worthy of further exploration using this dataset. These include, for example, looking at treatment approaches and functional outcomes of people who used primarily wheelchairs for their locomotion and exploring how particular risk factors associated with poorer functional outcomes after rehabilitation, such as bowel and bladder incontinence or depression, influenced the physical therapists' selection of therapeutic activities.

CONCLUSIONS

Overall, this study found that people in poststroke rehabilitation are receiving therapy that is generally consistent with a task-based training approach. Physical therapists focus their treatment strongly on the task of gait. Therapists adapt their training for people with more impaired walking ability and as patients progress through the rehabilitation process. However, a small percentage of time during inpatient therapy is spent on advanced mobility activities, and many people do not practice walking in the community with a physical therapist before discharge home. This is a concern, given evidence supporting the influence that the environment has on task difficulty and the challenges that patients face when they return to their homes and communities from an inpatient setting.

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APPENDIX 1: PT INTERVENTION DOCUMENTATION FORM

Physical Therapy Rehabilitation Activities

6649 Patient ID: Sample

Date of Therapy Session: / /

Therapist:

Time session begins: :

INTERVENTION CODES

Neuromuscular Interventions:
01. Balance training
02. Postural awareness
03. Motor learning
04. PNF
05. NDT
06. Gait with body weight support
07. Involved upper extremity addressed
08. Constrained induced movement therapy

Musculoskeletal Interventions:
09. Strengthening
10. Mobilization
11. PROM/Stretching
12. Manual Therapy
13. Motor Control

Cardiopulmonary Intervention:
14. Breathing
15. Aerobic/Conditioning exercises

Cognitive/Perceptual/Sensory Interventions:
16. Cognitive training
17. Perceptual training
18. Visual training
19. Sensory training

Education Interventions:
20. Patient
21. Family/Caregiver
22. Staff

Equipment Interventions:
23. Prescription/Selection
24. Application
25. Fabrication
26. Ordering

Modality Interventions:
27. Electrical Stimulation
28. Biofeedback
29. Ultrasound

Pet Therapy:
30. Use of dog
31. Use of other animal

Assistive Device:
32. Ankle dorsi flex assist
33. Cane - Large base
34. Cane - Small base
35. Cane - Straight
36. Crutches - Axillary
37. Crutches - Forearm
38. Crutches - Small base forearm
39. Dowel
40. Grocery cart
41. Hemirail
42. Ironing board
43. KAFO
44. Lite gait
45. Mirror
46. Parallel bars
47. Platform (parallel bars or FWW)
48. Standing frame
49. Steps (various heights)
50. Step ladder
51. Swedish knee cage
52. Swiss ball
53. Tray table
54. Walker - FWW
55. Walker - Hemiwalker
56. Walker - Rising Star
57. Walker - Standard
58. Wheelchair

Other:
59.

Area Involved/non-functional:
60. Upper Extremity
61. Lower Extremity
62. Trunk
63. Head/Neck

	Duration of Activity: Enter in 5 minute increments.	Interventions: Enter one intervention code per group of boxes.
Pre-Functional Activity		
Bed Mobility		
Sitting		
Transfers		
Sit-to-Stand		
Wheelchair Mobility		
Pre-gait		
Gait		
Advanced Gait		
Community Mobility		
Intervention not related to functional activity		
Intervention #2 not related to functional activity		

Co-Treat:
No. of minutes: Disciplines:

Patient Assessment:
Formal Assessment (initial, re-evaluation, discharge): minutes
Home Evaluation: minutes
Work Site Evaluation: minutes

Physical Therapy Time:

Physical Therapist	PT Assistant	PT Aide/Tech	PT Student
minutes	minutes	minutes	minutes

Group Physical Therapy Time:
PT Group/Dovetail: minutes
Enter the number of each that participated in the Group PT:

Patients	Therapists	Assistants	Aides/Techs	Students

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Abbreviations: FWW, front-wheel walker; KAFO, knee-ankle-foot orthosis; NDT, neurodevelopmental treatment; PNF, proprioceptive neuromuscular fasciculation; PROM, passive range of motion.

APPENDIX 2: FIM LOCOMOTION ITEM SCALE

Locomotion/walk: Includes walking, once in a standing position, on a level surface.

No Helper	
7	Complete independence: subject walks a minimum of 150ft (50m) without assistive devices. Performs safely.
6	Modified independence: subject walks a minimum of 150ft (50m) but uses a brace (orthosis) or prosthesis on leg, special adaptive shoes, cane, crutches, or walkerette; takes more than reasonable time or there are safety considerations.
5	Exception (household ambulation): subject walks only short distances (a minimum of 50ft [17m]) with or without a device. Takes more than reasonable time or there are safety considerations.
Helper	
5	Supervision: subject requires standby supervision, cuing, or coaxing to go a minimum of 150ft (50m).
4	Minimal contact assistance: subject performs 75% or more of locomotion effort to go a minimum of 150ft (50m).
3	Moderate assistance: Subject performs 50% to 74% of locomotion effort to go a minimum of 150ft (50m).
2	Maximal assistance: Subject performs 25% to 49% of locomotion effort to go a minimum of 50ft (17m). Requires assistance of one person only.
1	Total assistance: subject performs less than 25% of effort, requires assistance of 2 people, or does not walk a minimum of 50ft (17m).

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ORIGINAL ARTICLE

Characterizing Occupational Therapy Practice in Stroke Rehabilitation

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ABSTRACT. Richards LG, Latham NK, Jette DU, Rosenberg L, Smout RJ, DeJong G. Characterizing occupational therapy practice in stroke rehabilitation. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S51-60.

Objectives: To describe how occupational therapy (OT) activities during stroke inpatient rehabilitation vary by admission functional status and over time and how time spent in these various activities relates to functional status at discharge.

Design: Observational cohort study.

Setting: Six inpatient rehabilitation hospitals in the United States.

Participants: People (N=713) receiving 4 to 19 hours of poststroke OT.

Interventions: Not applicable.

Main Outcome Measures: Patients were categorized by number of 4-hour blocks of OT received and by admission upper-extremity (UE) dressing score on the FIM instrument. In each group, the percentage of time spent in 16 activities and the percentage of patients who received each activity were calculated. The amount of time in activities was compared for those patients scoring 1 or 2 at admission who achieved at least a level of supervision for UE dressing (a score of ≥5) using Wilcoxon 2-sample tests.

Results: The majority of OT time was spent in impairment-focused activities (37.5%) or training basic activities of daily living (31.9%). Treatment progressed to more advanced activities over time (eg, less bed mobility, more home management), yet little time was spent on community integration or leisure activities and with very few patients. Successful patients received more higher-level activities, whereas unsuccessful patients received larger amounts of basic-level activities.

Conclusions: OT activities focused on a combination of remediating impairments and retraining specific functional tasks, at the ability level of each individual patient, and provided higher-level activities as patients improved their function. More time in higher-level activities was related to greater success in rehabilitation. However, higher-level activities remain the least common activities provided during inpatient rehabilitation.

Key Words: Activities of daily living; Clinical practice patterns; Cerebrovascular accident; Occupational therapy; Rehabilitation.

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A DETAILED LITERATURE REVIEW substantiating the need to examine multidimensional rehabilitation processes to improve outcomes for specific types of patients is presented elsewhere.[1] Also described elsewhere is an introduction on where this study's research methodology fits into the pantheon of biomedical and clinical research methodology.[2]

Occupational therapists play a key role in poststroke rehabilitation. People with stroke make up the most common diagnostic group served by occupational therapists.[3-5] However, precise descriptions of activities occupational therapists provide to patients undergoing inpatient stroke rehabilitation are lacking. The Occupational Therapy Practice Framework[6] asserts that occupational therapists should address ability to participate in activities in a variety of life roles. The process for facilitating participation in stroke rehabilitation can include a mixture of remediation, compensatory techniques, and preventative intervention. Knowledge of which occupational therapy (OT) process combinations are best for facilitating successful rehabilitation outcomes is not known.

Several recent systematic reviews suggest that OT improves the performance of some functional tasks and reduces impairments after a stroke.[7-9] A few observational studies describe the nature of OT interventions currently being used for stroke rehabilitation. For the most part, such studies have been conducted in countries outside the United States,[10-12] have described treatment only in terms of duration or frequency,[10,13,14] or have involved a limited number of patients.[11,12] Keren et al[15] found that OT provided more intensely was associated with more cognitive improvement and higher scores on the cognitive domains of the FIM but did not describe the actual activities provided by these occupational therapists. The National Board for Certification in Occupational Therapy Practice Analysis reported the frequency with which entry-level practitioners used specific interventions but did not break these down by patient condition and only surveyed occupational therapists within the first 3 years of their practices.[5]

Recently, only 2 studies have examined in detail the content of OT in inpatient stroke rehabilitation. Bode et al[16] surveyed the content of therapy for 177 patients with stroke undergoing 2 to 5 weeks of inpatient stroke rehabilitation across 8 acute and 5 subacute settings in the United States between 1993 and 2000. Health care providers in these settings recorded time spent across 5 activity categories (evaluation and screening, activities of daily living [ADLs] and instrumental activities of daily living [IADLs], interventions for performance skills or

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body structure and function impairments, discharge planning, or case management) in 15-minute increments. They found that occupational therapists spent most of their time providing interventions that addressed performance skills or body structure and function impairments, such as motor rehabilitation, cognitive retraining, or therapeutic equipment.

As part of the Post-Stroke Rehabilitation Outcomes Project (PSROP), members of our group created a taxonomy of activities used in OT.[17] This taxonomy provides details about treatments and therapeutic activities that therapists used throughout the rehabilitation stay. We recently reported on the percentage of time in OT that 954 patients spent in the 16 OT activities during inpatient poststroke rehabilitation.[18] Although we organized our activities somewhat differently from Bode et al,[16] we also found that occupational therapists spent almost half of the therapy time using activities that directly targeted remediating performance skills or body structure and function impairments (ie, upper-extremity [UE] control, sitting balance, bed mobility, wheelchair, prefunctional, transfers). The second most common set of activities provided was the practice of basic ADLs (BADLs). A variety of intervention techniques were associated with each activity.

Our previous report described OT activities provided for patients undergoing inpatient stroke rehabilitation without concern for the functional levels of patients. However, occupational therapists most likely base intervention selections on the impairment and activity limitations of each patient, as well as the amount of therapy time that will be tolerated by each patient. In addition, it is likely that the types of activities and interventions that are provided vary across a patient's rehabilitation stay. These ideas receive support from the Bode[16] study, in which the amount of time spent in ADLs and IADLs versus impairment-focused activities varied somewhat with length of stay and whether a patient was more or less impaired. Therefore, in this report, we provide a more detailed description of OT for people undergoing stroke rehabilitation by classifying patients on the basis of amount of OT received and amount of limitation exhibited in ADL performance at admission. We then describe OT activities that therapists provided as interventions across the rehabilitation episode.

METHODS

The methodology governing the full PSROP, provided in this supplement by Gassaway et al,[19] presents a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, and a detailed description of the project's final study group. The methodology is summarized in Maulden et al.[20] The institutional review boards at Boston University and at each participating inpatient rehabilitation facility (IRF) approved the study.

Patients in the OT Subset

We examined a subset of the PSROP U.S. database that received at least 1 OT session during rehabilitation as documented on project point-of-care OT intervention documentation forms. OT sessions were documented for 1096 U.S. patients (94% of the 1161-subject U.S. sample).

The next step was to identify the amount of OT services that patients received. The amount of OT received was divided into 4-hour blocks. Those 713 patients who had at least 1 four-hour block and less than 5 four-hour blocks of therapy were selected for analysis in this report. We chose this group of patients because our data showed that patients with less or more time in rehabilitation may have had important differences in illness severity and function from the group receiving 3 to 19 hours of therapy.

Instrumentation

The OT intervention documentation form (appendix 1) developed for the PSROP included a taxonomy of information such as targeted activity area, interventions used by the clinician within each activity, and duration of each activity, measured in 5-minute increments. Activity categories included prefunctional, bed mobility, sitting balance, UE control, transfers, wheelchair management, bathing, grooming, dressing, toileting, feeding, functional mobility, home management, community integration, and leisure. Definitions for the activities and interventions contained on the OT intervention documentation form were provided to practicing clinicians and are available on request. Additional information, such as whether the session was individual or group, time spent in evaluation and planning, and potentially influential professional discussion of the patient among colleagues, was also obtained. One OT intervention documentation form was completed for each OT session a patient received during his/her inpatient rehabilitation stay.

A lead occupational therapist from each IRF participated in a train-the-trainer teleconference to learn how to use and teach others to use the OT intervention documentation form. After the teleconference, the lead occupational therapists trained colleagues in their respective IRFs.

Each site incorporated auditing of intervention documentation form use into routine site practices. Typically, the lead occupational therapists observed a patient session and completed a separate intervention documentation form based on what was observed. The therapist providing the session completed a form as per protocol. The lead therapist reviewed and discussed differences in completion with the practicing therapist.

Face validity was built into the intervention documentation forms as they were developed and used by IRF therapists as described above. Predictive validity was assessed by showing significant effects of OT interventions (and other therapy interventions) on outcomes.[21-23] For example, the amount of variation explained in discharge FIM score, controlling for patient characteristics (including admission FIM score, severity of illness, and demographic factors), was 40% for moderate strokes and 45% for severe strokes. When total time per day spent on physical therapy (PT), OT, and speech-language pathology (SLP) was added, there was no increase in variation explained for discharge FIM score, consistent with previous findings by Bode[16] However, when time per day spent in specific PT, OT, and SLP activities was added, the amount of variation explained increased to 52% for moderate strokes and 68% for severe strokes, adding 12% to 23% explanation of variation, respectively, in discharge FIM scores.

Functional performance for each study patient at admission to and discharge from inpatient rehabilitation was obtained via retrospective chart review using the study site's reporting of the FIM.[24,25] We assumed all clinicians providing FIM data within IRFs as part of standard practice were FIM credentialed; no additional documentation of FIM elements was performed for project purposes. We categorized our sample by a representative admission functional status score on the FIM. The UE dressing score was selected as our categorizing variable because dressing practice was one of the most frequently reported activities provided to this group of patients,[18] and because only 3 patients were more independent in lower extremity than UE dressing at baseline. Appendix 2 provides a description of FIM levels for the UE dressing component.

Data Analysis

Patients were divided into those who received 1, 2, 3, or 4 four-hour blocks of OT. Because data concerning activities were collected across an entire session and because OT sessions differed in length, each 4-hour block of therapy could contain a variable number of sessions. Therefore, we classified patients using the number of full sessions that would bring the therapy hours the closest to 4, 8, 12, and 16 hours of OT without including the next time block. For example, patients classified as having 1 four-hour block of therapy received between 3 and 4.75 hours of OT during their rehabilitation stay. For each group, descriptive statistics were derived to examine patients' demographics and processes of care. Then, because we believed that the content of therapy is driven by the severity of patients' deficits and activity limitations, we grouped patients by FIM UE dressing scores: 1 or 2, 3 or 4, or 5 or more.

For each OT duration (eg, number of 4-h blocks) and UE dressing FIM score group, we first determined the percentage of time spent in assessment and then determined the percentage of all nonassessment OT time across blocks and for each block of therapy spent directed to each OT activity. In addition, we examined the amount of time spent in home assessment. Second, we wanted to determine whether the amount of time spent in any of these activities was associated with better outcomes. To do this, we examined the group of patients who required the most assistance in UE dressing at the start of rehabilitation (those scoring 1 or 2 on the FIM UE dressing item). We defined attaining a level of supervision or better for UE dressing (a score of ≥ 5 on the FIM UE dressing item) at discharge as successful rehabilitation. We ran Wilcoxon nonparametric 2-sample tests comparing mean percentage time spent in each activity between those who achieved a 5 or greater on the FIM UE dressing item and those who failed to achieve such a result. Because this analysis was considered exploratory in nature, we did not control for simultaneous error rates.

RESULTS

Table 1 gives the demographic, process, and outcome variables for patients in this analysis. Generally, patients with longer durations of OT had a longer time period from onset of stroke to rehabilitation admission, a lower admission motor FIM score, and slightly lower admission cognitive FIM scores. Thus, patients with more functional deficits received more OT. Approximately the same percentage of patients in each group returned home. Patients' time in OT was divided into 4-hour blocks of therapy. Each block ranged, on average, from 223.6 to 242.1 minutes and consisted of between 5.2 and 6.8 sessions across 4 to 8 days. It appeared that occupational therapists designed therapy based more on the level of dysfunction of each patient and changed therapy across the rehabilitation episode rather than the amount of time the patient was in

Table 1: Characteristics of Patient, Process, and Outcome Variables by Amount of OT Received

PSROP Variable	No. of 4-Hour Blocks of OT			
	1 (n=188)	2 (n=209)	3 (n=175)	4 (n=141)
Patient characteristics				
Mean age (y)	67.1	68.2	66.2	66.4
Race (%)				
White	53.2	58.4	58.3	63.1
Black	26.1	25.4	24.6	20.6
Other, including Hispanic	20.7	16.2	17.1	16.3
Sex (% men)	48.4	51.2	49.7	49.7
Type of stroke (%)				
Hemorrhagic	25.5	25.8	27.4	22.0
Ischemic	74.5	74.2	72.6	78.0
Side of stroke (%)				
Left	40.4	38.8	45.1	41.8
Right	46.8	46.4	41.7	51.1
Bilateral	10.1	12.9	10.9	5.0
Unknown	2.1	2.3	1.9	2.7
Mean admission motor FIM score	45.2	40.6	38.5	36.0
Mean admission cognitive FIM score	21.7	21.5	21.3	20.2
Mean days from symptom onset to rehab admission	10.3	12.5	14.7	16.6
Process variables				
Mean length of stay	10.7	14.8	19.0	23.1
Mean total minutes of OT	291	523	759	996
Mean total no. of OT sessions	7.2	13.1	19.2	26.9
Outcome variables				
Discharge disposition (%)				
Home	79.8	80.9	75.4	80.1
Board and care (assisted living)	0.5	1.9	2.9	5.5
Skilled nursing facility	8.5	12.4	18.3	12.8
Acute care hospital (own or other facility)	9.0	2.9	0.6	0.7
Other rehabilitation facility	2.1	2.4	2.9	0.7
Mean discharge motor FIM score	63.0	63.8	61.8	60.6
Mean discharge cognitive FIM score	25.3	25.5	25.1	25.3

Abbreviation: rehab, rehabilitation.

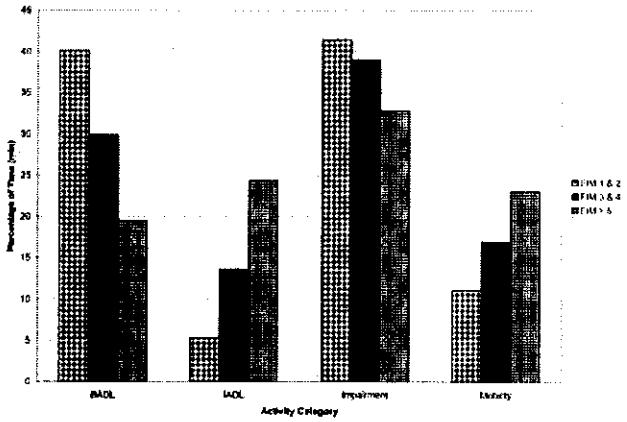

Fig 1. Amount of time spent in activity categories for patients with 1 four-hour block of therapy across admission FIM UE dressing scores.

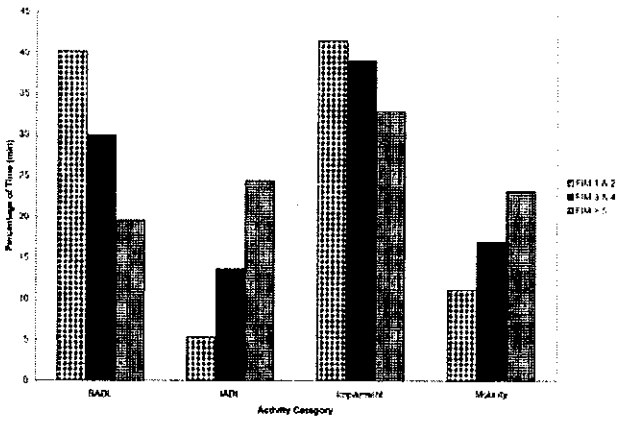

Fig 3. Amount of time spent in activity categories for patients with 3 four-hour blocks of therapy across admission FIM UE dressing scores.

rehabilitation. However, in general, occupational therapists provided each activity to a larger percentage of patients as the number of OT blocks provided increased. To understand patterns in the data, we divided activities into 4 categories: BADL training, IADL training, impairment-focused activities (those targeting performance skill or body structure and function impairments—eg, UE control or prefunctional activities), and mobility activities. Figures 1 through 4 show the pattern of time spent in each therapy across admission FIM UE dressing levels.

Occupational therapists provided both basic impairment-focused activities and BADLs to a majority (n=672) of patients. In general, impairment-focused activities were the most, and BADLs the second most, frequently provided activities (37.5% and 31.9% of therapy, respectively). Of the impairment-focused activities, the least amount of time was spent working on activities to improve sitting balance and the most time was spent providing UE control activities. In fact, UE control was the most frequently provided activity across activities (except for the 2-block, FIM 1 or 2 group). The most frequently provided BADL activity was dressing training; the least amount of time was spent in feeding.

Therapists tailored therapy to patients' levels of dysfunction in these activities. Typically, the amount of time occupational therapists spent in impairment-focused and BADL activities decreased as admission FIM UE dressing level increased, regardless of how many blocks of OT patients received.

Occupational therapists provided IADL training to 75.5% of patients. For all patient groups, the percentage of patients given IADL training and the amount of time spent in IADL training increased as FIM UE dressing level increased. Home management activities were the most frequent activities provided, but occupational therapists devoted little time to either community integration or leisure activities (<10% of time to community integration, <5% to leisure) for any of the patient groups. Occupational therapists performed few home evaluations (0%–7.9% of patients received a home evaluation, with no more than 1.8% of time spent on home evaluation), despite a large percentage of patients returning home. Sixty-nine percent of patients who were discharged home received recommendations for follow-up therapy (home health or outpatient).

Mobility training was provided to 88.4% of patients. In general, occupational therapists spent more time working on mobility skills with patients with higher FIM UE dressing

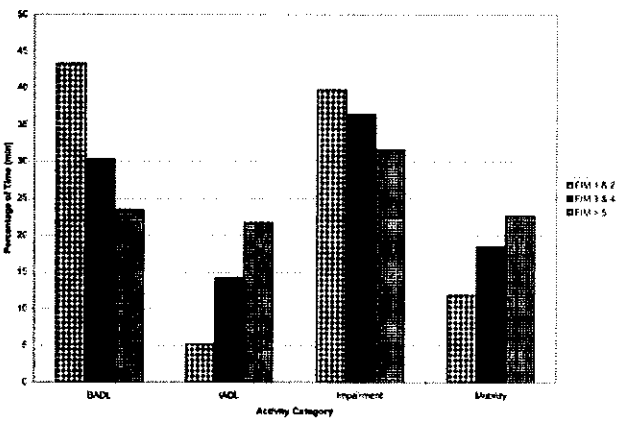

Fig 2. Amount of time spent in activity categories for patients with 2 four-hour blocks of therapy across admission FIM UE dressing scores.

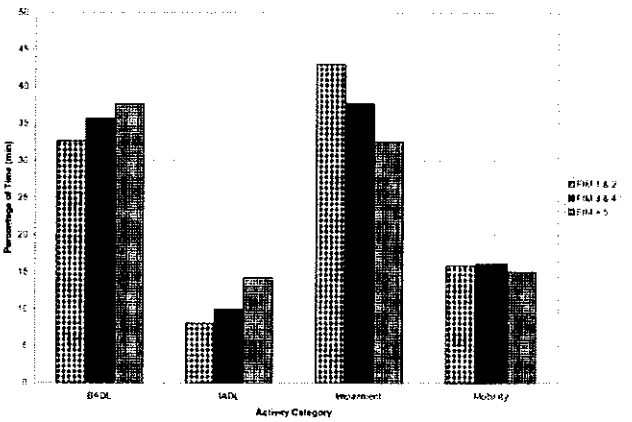

Fig 4. Amount of time spent in activity categories for patients with 4 four-hour blocks of therapy across admission FIM UE dressing scores.

scores. The pattern of time spent in each activity varied. Although transfer training was the most frequent mobility training provided for those patients with admission FIM UE dressing scores of 1 or 2, functional mobility training was the most frequently provided mobility training for most patients who had FIM UE dressing scores of 3 to 5.

We were also interested to know whether the amount of time spent in more basic activities decreased and that spent in more complex activities increased across the rehabilitation episode as patients presumably improved in function. Indeed, this was generally the case. The amount of time in the following basic activities typically decreased the longer a patient was in therapy: dressing, grooming, feeding, bed mobility, and sitting balance. More complex activities of home management, functional mobility, community integration, and leisure tended to increase the longer patients were in rehabilitation.

Relation of Activities to Outcome

One hundred fifty-two patients started rehabilitation at a dependent or maximum-assist level of UE dressing. Forty-seven achieved at least a supervised level of independence in UE dressing by discharge, and 105 did not. Table 2 describes the mean percentage of time spent in each activity for those patients with and without a successful UE dressing outcome. First, it is important to notice that although we defined success based on the UE dressing item of the FIM, all FIM item scores are lower for the nonsuccessful group than for the successful group. Those who were successful at obtaining a FIM UE dressing score of at least 5 were provided with a greater amount of time in higher-level activities such as community integration, functional mobility, home management, and leisure activities. In contrast, patients who failed to obtain a score of 5 or greater on the FIM UE dressing item received more OT directed toward the lower-level activities of wheelchair management, sitting balance, grooming, and feeding. The percentage of time spent on toileting, transfers, UE control, bathing, bed mobility, and dressing did not differentiate those who succeeded from those who failed to obtain at least a supervised level in UE dressing activities.

Table 2: Mean Percentage of Time Spent on Therapeutic Activities by UE Dressing Outcome

PSROP Variable (mean % of time)	Achieved ≥5 on FIM UE Dressing Item at Discharge		Wilcoxon 2-Sample Test	
	Yes	No	*t*	*P*
Formal assessment	8.2	6.8	4014.5	.090
Home assessment	0.6	1.0	3582.0	.882
Bathing	4.0	5.1	3302.5	.217
Bed mobility	1.2	1.8	3423.5	.462
Feeding	2.1	4.2	3110.0	.032
Dressing	19.5	19.7	3577.5	.943
Functional mobility	6.5	2.7	4281.5	.005
Grooming	5.1	9.0	2887.0	.005
Leisure	3.0	1.4	4015.0	.029
Toileting	2.8	2.6	3681.0	.718
Transfers	6.7	6.8	3713.0	.635
Sitting balance	2.6	6.1	2912.0	.005
UE control	25.6	23.6	3889.5	.241
Wheelchair management	0.5	1.5	3123.5	.016
Prefunctional	12.8	12.7	3651.0	.825
Home management	4.9	1.6	4357.0	.000
Community integration	2.7	0.8	4034.5	.013

NOTE. Patients at a dependent (FIM score, 1) or maximum-assistance (FIM score, 2) level in UE dressing at admission. Outcome: attain at least a supervised level of function in UE dressing at discharge.

DISCUSSION

According to the Occupational Therapy Practice Framework,[6] occupational therapists should assist patients in regaining the ability to complete activities across multiple life roles. These activities include BADLs, home management, work or school activities, and leisure or recreation. Facilitating increased independence and participation can be achieved either by modifying tasks and adapting environments, by decreasing impairment in body structures and functions, or a combination of approaches. Therapists are encouraged to tailor therapy to the needs of patients and the likelihood of goal attainment within the amount of therapy time available. Therefore, to expand our original report in which we catalogued time spent in OT activities across all PSROP patients with stroke, in this report we analyzed time spent in these activities based on the amount of disability exhibited by each patient (represented by the FIM UE dressing item score) and the amount of OT the patient received. In addition, it is expected that therapy should change as patients gain in skill. Hence, we also analyzed how the amount of time spent in OT activities changed across the rehabilitation episode.

Do Occupational Therapists Use a Strategy of Task Training or Restoration of Body Structure and Function?

Our data show that occupational therapists frequently use a combination of approaches. For all but 1 patient group, the most common group of activities provided to these patients undergoing inpatient stroke rehabilitation was impairment-focused activities, followed by BADL training. This finding is similar to that of Bode et al,[16] who reported that occupational therapists spent more time providing impairment-focused than functional activities to most of their patients. The 2 activities that occupational therapists spent the most time delivering were UE control and dressing activities. Thus, it appears that occupational therapists value the practice of actual daily tasks but also view the motor impairments caused by stroke to be a significant problem that needs to be addressed in therapy.

Do Occupational Therapists Address Activities Across Life Roles?

Our data indicate that the kinds of activities addressed in OT during inpatient stroke rehabilitation were restricted. Basic self-care activities were provided to nearly all patients, with a large percentage of time spent in these activities. IADLs involved in home management, however, were primarily provided to those patients with greater function at admission, probably because therapy time for patients at a lower functional level was spent on more basic activities. In addition, very little time was spent providing leisure activities to a very small number of patients. What is more disconcerting is how little attention is paid to community integration activities, which in our study was defined with a heavy emphasis on community mobility. Difficulty being mobile in the community (getting into and out of a car, driving, using public transportation) severely restricts participation in activities outside the home and precludes many recreation and social activities. These data underscore the need for adequate community-based therapy services to facilitate independence in community participation—unfortunately at a time when the amount of therapy

patients receive from outpatient or home health services has decreased dramatically.[26]

The lack of attention to these higher-level activities may stem from several sources. One possibility is short rehabilitation stays combined with the view that the ability to perform more basic activities is a precursor to training higher-level activities. Such a view may not be unfounded. The belief that improving basic motor skills will lead to increased function is inherent to motor rehabilitation, and several studies have shown that improvements in motor skills is associated with increases in functional ability.[27,28] In addition, inability to complete basic self-care activities independently or at least with minimal assistance often determines whether patients are discharged to the community, where they have the opportunity to engage in higher-level activities. It is possible that were rehabilitation stays longer, therapists would provide more advanced activities later on in the rehabilitation episode. This idea receives some support from our data, which show that more patients were provided with and increased time was spent in these activities as the rehabilitation episode progressed. Another possible contributor to the focus on more basic activities could be the use of the FIM instrument itself. Rehabilitation hospitals use changes in FIM scores as quality indicators of success in rehabilitation. However, the FIM was designed only to measure BADLs and, as such, does not capture patients' performances in more advanced participation activities.

The small amount of leisure training provided by the occupational therapists in our study may reflect the fact that the therapists worked on health care teams that also included recreation therapists. Therefore, despite the OT profession endorsing leisure activities as falling within the domain of OT, leisure training and counseling on these teams may have been the province of recreation therapists.

Do Occupational Therapists Tailor Therapy Based on Patient Disability?

We found partial evidence to suggest that occupational therapists tailored therapy based on patient functional level, both at admission and as patients recovered. For example, less time was spent in low-level activities (eg, grooming, sitting balance, bed mobility) with those patients scoring at a FIM UE dressing level 5 or above compared with those scoring at levels 1 or 2, whereas the amount of time spent in the higher activities of functional mobility and home management was greater for the former group of patients. A larger amount of time was spent on higher-level activities, such as functional mobility and home management and less time on more basic activities (eg, sitting balance) later in the rehabilitation episode. Bode et al[16] also found that for some groups of patients, occupational therapists tailored their activities based on patient disability. For example, for patients with 2-week rehabilitation durations, occupational therapists provided more functional activities to those with less disability compared with more impairment in the last week of rehabilitation, whereas the reverse was seen for those with 5-week stays. However, because they did not break down their functional category into BADLs, IADLs, and mobility, nor into higher- or lower-level activities within those categories, direct comparisons between their study and ours is not possible.

However, the amount of time spent in dressing and UE control activities remained substantial. This may reflect the breadth of those categories. Dressing tasks, for example, range from the simple—putting on a T-shirt—to the complicated—donning of a brassiere or tying shoelaces. UE control ranges from simple 1-joint proximal movements to tasks such as piano playing, which requires exquisite fine motor control. In addition, the affected UE poststroke has been particularly resistant to recovery to a functional capacity, most likely because of the level of coordination required to have a functional hand.[29] As UE function improved, BADL training may have progressed from compensatory training to a more remedial approach in which emerging UE motor skills were incorporated into BADLs. Therefore, it is likely that patients experienced a continued need for UE training and BADL training throughout the rehabilitation episode. Because we did not collect data about subactivities within each BADL category (ie, putting on a T-shirt and fastening a hook closure; both were categorized as dressing yet require very differing motor skills), actual therapy differences between patients of different functional levels could not be detected by these categories.

Although we found that occupational therapists customized therapy based on patient disability, we found little evidence to suggest that therapy was tailored based on the amount of OT provided. Because most patients eventually were referred to outpatient or home health therapy, therapists in the inpatient rehabilitation setting may believe that their therapy only begins the process of facilitating independence. Therapy does not need to be limited if there is a belief that continued training will be available once a patient leaves the facility. However, this belief may be erroneous given the decreased amount of therapy time that patients receive from outpatient or home health services.[26] Although occupational therapists did not seem to alter activities provided based on amount of time available in rehabilitation, they might have altered specific methods used for training within these activities. For example, they may have provided more compensatory than remedial training when rehabilitation stays were shorter. The current data do not speak to whether such alterations in OT intervention techniques occur.

Is the Amount of Time in OT Activities Related to Functional Outcome?

The intent of rehabilitation is to promote independence in functional activities. There has been little evidence to date to guide therapists in treatment planning. However, there have been studies finding that OT can improve task performance and reduce impairments after stroke.[7-9] There is a great need to examine which aspects of OT practice are and are not effective. In this study, we examined the relation between amount of time spent in various OT activities with outcomes in UE dressing skill for those patients who were admitted to rehabilitation at a dependent or maximum-assist level of independence in UE dressing. Those patients who successfully achieved at least a supervised level of UE dressing had been provided with larger amounts of therapy directed at higher-level activities than those who were unsuccessful in achieving this level of independence. This result is similar to that found in the study by Latham et al,[21] in which more PT time in advanced gait activities was found for those patients with greater success in rehabilitation. It may be that practicing the types of motor and cognitive processing required of these higher-level activities facilitates gains in independence in other areas of daily functioning. Alternatively, it may be that those patients who were successful in rehabilitation received greater amounts of higher-level activities because they experienced more recovery and were better able to engage in such activity practice.

We were surprised that amount of time spent in dressing activities did not delineate those who were successful in UE dressing recovery from those who were not. We would have expected an increased amount of time spent in dressing activities to be associated with an item on the FIM measuring dressing ability. One possible reason that this was not so is that the activity category of dressing covers a wide range of activities, from putting on a shirt or pants to tying shoelaces. It may

be that both groups received a similar amount of dressing training but that this training emphasized different dressing activities.

We also were surprised that the most frequently provided activity was not associated with successful outcome. On average, occupational therapists spent nearly a third of their time providing UE control activities, yet this training was not associated with success in UE dressing. There are several possible reasons for this. First, it must be emphasized that our definition of success was limited solely to reaching a supervised or higher level of independence in UE dressing, rather than independence across multiple meaningful daily activities. It may be that UE training better facilitates independence in other activities.

Second, BADL training in stroke rehabilitation consists largely of teaching compensatory techniques for completing activities, such as 1-handed dressing techniques and prescribing adapted equipment to make 1-handed dressing activities easier (eg, providing a button hook). These techniques train a patient not to use his/her affected UE. Thus, increasing motor skills may indeed be unrelated to improvements in UE dressing because the patient is attempting to complete UE dressing tasks without using the affected UE. In addition, compensatory training in BADLs and IADLs may actually contradict the UE control training by encouraging learned nonuse of the affected UE.

A third reason for the lack of impact of UE control training on UE dressing ability is that, although occupational therapists spent a large percentage of their time on UE motor rehabilitation, in actual minutes this only averaged 10 to 12 minutes of direct UE motor control practice per session (although motor practice may have occurred during activities targeting other skills as well). This paucity of time devoted to motor practice contradicts an accepted principle of movement therapy: that intensity of practice is important.[30] Such a modest amount of time spent in training a motor skill is unlikely to facilitate enough motor recovery to affect dressing ability. Intensive therapy is an accepted principle of movement therapy.

In contrast, those patients who were unsuccessful at achieving a supervision level of independence in FIM UE dressing at discharge spent larger amounts of time in several lower-level activities than patients who were successful. These activities included wheelchair management, sitting balance, grooming, and feeding. Because these are more basic, it is likely that the amount of time spent in these activities reflects patient abilities. However, these data suggest that, at least for UE dressing, spending more time in these basic activities is not facilitating increased independence in this population. Obviously, this type of analysis will need to be repeated with outcomes in other patient-relevant activities and with other groups of patients with stroke to determine whether or not increased time on basic activities fails to promote improvements in function. Nonetheless, these data argue that it is important to understand the limits of our therapies in reaching certain functional outcomes.

Several limitations of this study warrant caution during interpretation of the results. The data about time in therapy activities and the percentage of patients who received each activity were gathered by therapists' reports. The therapy staff of each participating facility was highly engaged in the project. However, self-reports are open to several biases, such as social desirability. Although therapists were trained and given explicit definitions of activity categories, validation of how therapists classified the activities that they were providing was performed at the site level and may have been inconsistent among sites. Also, not all activity categories were mutually exclusive, either in definition or in clinical practice, which might have made it difficult for therapists to document which activity they were providing. For example, some mobility tasks could have fit in either bed mobility or functional mobility based on the definition, and a therapist could have been working on UE motor control simultaneously with dressing or grooming; however, there was no way to categorize more than 1 activity per 5-minute period. Another limitation is that we had only FIM scores available rather than impairment-level information for categorizing patient groups and outcomes. Occupational therapists most likely base treatment decisions on both client disability and impairments. Because patients can be heterogeneous in impairments and be in the same functional level, it is likely that different therapy treatments would be used with these patients. Also, we had no information about functional abilities in activities other than BADLs. Although independence in BADLs is important, it is far from a sufficient condition for full community participation and a satisfying quality of life. Rehabilitation should improve patients' quality of life.

Nonetheless, the aim of this study was to explore functional changes that take place within inpatient rehabilitation, and this study has numerous strengths in this area. It included a large number of geographically diverse patients in the United States, increasing the generalizability of these findings. The study used a detailed taxonomy of activities that was created by a team of both study personnel and practicing occupational therapists in the participating facilities, which resulted in data collection that was meaningful to practicing clinicians.

CONCLUSIONS

In this study, we examined types of activities that occupational therapists provided to patients during inpatient stroke rehabilitation. We discovered that occupational therapists provided a mixture of task training and restorative activities and that they tailored their therapy programs based on patient disability but did not seem to tailor therapy based on amount of OT. In patients who were admitted requiring at least maximum assistance in UE dressing, more time spent in higher-level activities (eg, community integration, functional mobility) was associated with a greater likelihood of reaching at least a supervised level of independence in FIM UE dressing.

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APPENDIX 1: OT INTERVENTION DOCUMENTATION FORM

Occupational Therapy Rehabilitation Activities

8646

Patient ID: Sample

Date of Therapy Session: / /

Therapist:

Time session begins: :

INTERVENTION CODES

Neuromuscular Interventions
01. Balance training
02. Postural awareness
03. Motor learning
04. PNF
05. NDT/Bobath
06. Brunstromm
07. Constrained induced movement therapy

Adaptive/Compensatory Interventions:
08. One-handed skills
09. Energy conservation
10. Environmental adaptation
11. Adaptive equipment

Musculoskeletal Interventions:
12. Strengthening
13. Mobilization, manual therapy
14. PROM/stretching
15. Edema control

Cardiopulmonary Interventions:
16. Breathing exercises
17. Aerobic/conditioning exercises

Cognitive/Perceptual/Sensory Interventions:
18. Cognitive training
19. Perceptual training
20. Visual training
21. Sensory training

Equipment Interventions:
22. Prescription/selection
23. Application
24. Fabrication
25. Ordering

Modality Interventions:
26. Electrical stimulation
27. Biofeedback
28. Hot/cold therapy

Education/Training Interventions:
29. Patient
30. Family/Caregiver
31. Staff

Assistive Devices:
32. Cane - Large base
33. Cane - Small base
34. Cane - Straight
35. Crutches - Axillary
36. Crutches - Forearm
37. Crutches - Small base forearm
38. Dowel
39. Grocery cart
40. Hemirail
41. Hi/low table
42. KAFO
43. Parallel bars
44. Platform (parallel bars or FWW)
45. Swiss ball
46. Tray table
47. Walker - FWW
48. Walker - Hemiwalker
49. Walker - Rising star
50. Walker - Standard
51. Wheelchair
Other:
52.

Area Involved:
53. Upper extremity
54. Trunk

Duration of Activity (Enter in 5 minute increments.) / **Interventions** (Enter one intervention code per group of boxes.)

- Pre-Functional Activity
- Bathing
- Dressing
- Grooming
- Toileting
- Feeding/eating
- Transfers
- Bed mobility
- Functional mobility
- Home management
- Community integration
- Leisure performance
- Upper extremity control
- Wheelchair management
- Sitting balance/trunk control
- Intervention not related to functional activity
- Intervention #2 not related to functional activity

Co-Treat:
No. of minutes: Disciplines:

Patient Assessment:
Formal Assessment (initial, re-evaluation, discharge): minutes
Home Evaluation: minutes
Work Site Evaluation: minutes

Occupational Therapy Time:
OT (minutes) / OT Assistant (minutes) / OT Aide/Tech (minutes) / OT Student (minutes)

Group Occupational Therapy Time:
OT Group/Dovetail minutes
Enter the number of each that participated in the Group OT:
Patients / Therapists / Assistants / Aides/Techs / Students

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Abbreviations: FWW, front-wheel walker; KAFO, knee-ankle-foot orthosis; NDT, neurodevelopmental technique; PNF, proprioceptive neuromuscular fasciculation; PROM, passive range of motion.

APPENDIX 2: COMPONENT OF DRESSING, UPPER BODY

Dressing, Upper body: Includes dressing and undressing above the waist, as well as applying and removing a prosthesis or orthosis when applicable. Performs safely.

No helper	
7	Complete independence: Subject dresses and undresses including obtaining clothes from their customary places such as drawers and closets; manages bra, pullover garment, or front-opening garment; manages zippers, buttons, or snaps; applies and removes prosthesis or orthosis when applicable. Performs safely.
6	Modified Independence: Subject requires special adaptive closure such as Velcro, or as assistive device (including a prosthesis or orthosis) to dress, or takes more than a reasonable amount of time.
Helper	
5	Supervision or Setup: Subject requires supervision (eg, standing by, cuing, or coaxing) or setup (application of an upper body or limb orthosis/prosthesis or setting out clothes or dressing equipment).
4	Minimal Contact Assistance: Subject performs 75% or more of dressing tasks.
3	Moderate Assistance: Subject performs 50% to 74% of dressing tasks.
2	Maximal Assistance: Subject performs 25% to 49% of dressing tasks.
1	Total Assistance: Subject performs less than 25% of dressing tasks, or is not dressed.

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ORIGINAL ARTICLE

Characterizing Speech and Language Pathology Outcomes in Stroke Rehabilitation

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ABSTRACT. Hatfield B, Millet D, Coles J, Gassaway J, Conroy B, Smout RJ. Characterizing speech and language pathology outcomes in stroke rehabilitation. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S61-72.

Objectives: To describe a subset of speech-language pathology (SLP) patients in the Post-Stroke Rehabilitation Outcomes Project and to examine outcomes for patients with low admission FIM levels of auditory comprehension and verbal expression.

Design: Observational cohort study.

Setting: Five inpatient rehabilitation hospitals.

Participants: Patients (N=397) receiving poststroke SLP with admission FIM cognitive components at levels 1 through 5.

Interventions: Not applicable.

Main Outcome Measure: Increase in comprehension and expression FIM scores from admission to discharge.

Results: Cognitively and linguistically complex SLP activities (problem-solving and executive functioning skills) were associated with greater likelihood of success in low- to mid-level functioning communicators in the acute poststroke rehabilitation period.

Conclusions: The results challenge common clinical practice by suggesting that use of high-level cognitively and linguistically complex SLP activities early in a patient's stay may result in more efficient practice and better outcomes regardless of the patient's functional communication severity level on admission.

Key Words: Auditory perceptual disorders; Clinical practice patterns; Problem solving; Rehabilitation; Speech therapy; Stroke.

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THE MIX OF SPEECH-LANGUAGE pathology (SLP) services in the poststroke population has been difficult to describe. Although there is a large body of literature that describes assessment, diagnoses, and activities involved in SLP services in the stroke population and the cognitive and communication sequelae that follow brain injury,[1-8] there is little to no research that adequately describes the interaction of these activities with the medical, physical, and emotional changes that occur with a stroke. SLP activities have been studied in isolation using broad categories based on speech and language diagnoses (ie, aphasia, dysarthria, dysphagia, cognitive-communication impairment). The interventions studied to date have been described subjectively or in structured research paradigms using a single selected treatment approach[9-12] and measuring change via performance on a specified task.

Many commonly used practices and treatment paradigms have little empiric evidence of their efficacy or effectiveness in the acute rehabilitation period. For example, use of group speech and language treatment has been studied in postacute populations[13,14] but not during the acute rehabilitation period. Although some universally validated practices exist in the area of diagnostics for the more tangible and technical aspects of SLP service provision (ie, modified barium swallow evaluations of dysphagia, video stroboscopic evaluations of vocal fold function), there is a paucity of data that describe the duration and timing of diagnostic activities and procedures as they relate to functional outcomes and success in SLP therapy.

Emphasis on achieving greater functional outcomes given diminishing lengths of stay (LOSs) during inpatient rehabilitation places clinicians in the daunting position of making constant adjustments to treatment plans based on each individual patient's needs. The complex nature of SLP services in stroke rehabilitation has limited the field's ability to conduct comprehensive studies that incorporate the interactions of comorbidities, leaving clinicians without firm guidance in how to prioritize activities while developing a treatment plan across a stroke patient's rehabilitation LOS. The policy of the American Speech-Language-Hearing Association is to provide evidenced-based practice, which is defined as "an approach in which current, high-quality research evidence is integrated with practitioner expertise and client preferences and values into the process of making clinical decisions."[15(p1)] However, there is no set protocol that describes which impairment to work on first or for what particular percentage of time, nor are there sufficient data to show that achieving a given performance level in a given area will enhance or detract from performance in other areas. It is left up to each individual clinician's instincts to adjust time spent in multiple activities using multiple interventions to try to achieve the most progress in the shortest possible period of time.

One of the primary reasons for the limitations in the current literature is the highly variable, complex nature of SLP activities and interventions. Rehabilitation of communication and swallowing is both an art and a science, and as yet, there has been no systematic way to compare practices or thoroughly capture what goes on during an inpatient rehabilitation stay and across settings. The objective of this article was to describe or characterize some basic aspects of SLP practice and the effects of specific SLP activities in achieving better outcomes for a subset of patients without a diagnosis of aphasia. We hypoth-

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esized that use of cognitively and linguistically complex SLP activities sooner in the rehabilitation stay is associated with better outcomes for patients who function as lower-level communicators at admission. This hypothesis stems from our clinical and anecdotal observations of patient performance and interactions in both one-on-one and group settings.

This article builds on the Post-Stroke Rehabilitation Outcomes Project (PSROP), a study of 1161 stroke rehabilitation patients discharged from 6 inpatient rehabilitation facilities (IRFs) in the United States. This article is limited to a subset of PSROP patients from 5 of these facilities. The motivation, purpose, scope, and key findings from the larger PSROP are provided in this supplement's introductory article.[16] A notable feature of the PSROP was the development of a taxonomy of rehabilitation activities and interventions associated with each clinical discipline, including SLP.[17] This taxonomy provided the methodologic breakthrough needed to characterize SLP activities and interventions discussed in the following sections.

METHODS

The methodology governing the full PSROP, provided in this supplement by Gassaway et al,[18] provides a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, data collection instruments, and a detailed description of the project's final study group. The methodology is summarized in Maulden et al.[19] The institutional review boards at Boston University and at each participating IRF approved the study.

Patients in the SLP Subset

We examined a subset of the PSROP database that received at least 1 SLP session during rehabilitation as documented on project SLP intervention documentation forms. SLP sessions were documented for over 90% of patients in 5 U.S. sites. In the sixth PSROP site, at least 1 SLP session during rehabilitation was documented for only 14% of patients; thus, this site was not included in the SLP analyses presented here. Deleting this 1 site entirely and all those patients with no documented SLP sessions in the other sites left a patient population of 936 patients from 5 sites.

The next step was to identify the amount of SLP services that patients received. To investigate the demographics and functional outcomes of this patieut population, the amount of SLP therapy received was divided into 3-hour blocks of time. For detailed analyses, we included all patients who received between 1 and eight 3-hour blocks (n=790) and excluded those patients who received less than 3 hours (n=86) or more that 24 hours (n=54) of SLP services. Because treatment approaches differ markedly between patients witb and without a diagnosis of aphasia, we chose to exclude patients with a diagnosis of aphasia anywhere in the medical record and focused on the larger sample of 599 patients who did not have a diagnosis of aphasia. We recognize that some of these patients may have had some poststroke aphasia but that the diagnostic label was not documented in the medical record.

Because we hypothesized that patients without an aphasia diagnosis who present with severe communication deficits experience a greater improvement in expressive and receptive communication when exposed to cognitively complex SLP interventions (eg, problem-solving activities), we compared 2 subsamples: 1 of lower-level functionally communicating patients and 1 of mid-level functionally communicating patients, as determined by admission FIM cognitive component (comprehension, expression) scores. Appendix 1 provides a description of FIM levels for these components.

Patient sample 1 (low-level functional communicators). Sample 1a includes only patients with admission FIM comprehension levels 1 through 3. This provided a sample of 176 patients (without an aphasia diagnosis, with admission FIM comprehension levels 1–3, with 1 to eight 3-hour blocks of SLP) for initial analyses. To further define the low-level sample, we examined another subset of these patients with low admission FIM expression (levels 1–3). Sample 1b contains 141 patients without an aphasia diagnosis with both admission FIM comprehension and expression levels of 1 through 3.

Patient sample 2 (mid-level functional communicators). Sample 2a (n=221) includes only patients without an aphasia diagnosis with admission FIM comprehension levels of 4 and 5 who received 1 to eight 3-hour blocks of SLP. Sample 2b includes a subset of these patients (n=144) who also have admission FIM expression levels of 4 and 5.

Table 1 describes demographic information for the 2 patient samples combined (mid-level and low-level groups) by 3-hour blocks of SLP therapy. Patients with admission FIM comprehension levels of 6 and 7 were not considered in the analyses because specific SLP goals would not likely address comprehension with patients performing at this level.

Instrumentation

The SLP intervention documentation form (appendix 2) developed for the PSROP[18] included a finite taxonomy of information, such as the targeted activity area, interventions used by the clinician, and duration of each activity. Interventions were recorded to capture the specific approach the clinician took in addressing SLP goals within an activity area. For example, during a problem-solving activity, a clinician may have used verbal cueing to implement analysis and synthesis strategies with the patient to facilitate generation of alternative solutions. In contrast, during a task to target auditory comprehension, a clinician may have used verbal cueing to introduce analysis and synthesis strategies for drawing appropriate inferences from the task stimuli. Definitions for the activities and interventions contained on the SLP intervention documentation form were provided to practicing clinicians and are available on request. Additional information such as whether the session was individual or group, time spent in evaluation and planning, and potentially influential professional discussion of the patient among colleagues was also obtained; however, specific subtest scores from standardized tests commonly administered in SLP practice were not obtained. One SLP intervention documentation form was completed for each SLP session a patient received during his/her inpatient rehabilitation stay.

A lead SLP therapist from each IRF participated in a train-the-trainer teleconference to learn how to use and teach others to use the SLP intervention documentation form. After the teleconference, the lead SLPs trained colleagues in their respective IRFs.

Each site incorporated auditing of intervention documentation form use into routine site practices. Typically, the lead SLP therapist observed a patient session and completed a separate intervention documentation form based on what was observed. The therapist providing the session completed a form as per protocol. The lead therapist reviewed and discussed differences in completion with the practicing therapist.

Face validity was built into the intervention documentation forms because they were developed and used by IRF therapists as described. Predictive validity was assessed by showing significant effects of SLP interventions (and other therapy interventions) on outcomes.[20-22] For example, the amount of variation explained in discharge FIM score, controlling for

Table 1: Characteristics of Patients Without Aphasia Diagnosis and With Admission FIM Comprehension Levels 1 Through 5 (n=397)

Characteristics	1 Block (n=87)	2 Blocks (n=97)	3 Blocks (n=69)	4 Blocks (n=45)	5 Blocks (n=30)	6 Blocks (n=30)	7 Blocks (n=22)	8 Blocks (n=17)	Total (n=397)	P
Demographic characteristics										
Mean age (y)	66.1	67.9	69.5	70.3	63.0	67.7	64.6	67.3	67.5	.352*
Sex (% men)	43.7	52.6	58.0	48.9	56.7	40.0	50.0	76.5	51.4	.211†
Race (%)										.207†
White	71.3	67.0	60.9	48.9	66.7	70.0	72.7	76.5	65.7	
Black	17.2	17.5	20.3	15.6	20.0	20.0	9.1	5.9	17.1	
Other, including Hispanic	11.5	15.5	18.8	35.6	13.3	10.0	18.2	17.7	17.1	
Health and functional status characteristics										
Type of stroke (%)										.384†
Hemorrhagic	28.7	21.7	23.2	42.2	30.0	30.0	27.3	29.4	27.7	
Ischemic	71.3	78.4	76.8	57.8	70.0	70.0	72.7	70.6	72.3	
Side of stroke (%)										.522†
Right	50.6	48.5	37.7	68.9	43.3	56.7	54.6	58.8	50.4	
Left	34.5	37.1	39.1	24.4	33.3	36.7	27.3	35.3	34.5	
Bilateral	12.6	10.3	20.3	6.7	20.0	6.7	13.6	5.9	12.6	
Unknown	2.3	4.1	2.9	0.0	3.3	0.0	4.6	0.0	2.5	
Location of stroke (%)										.056†
Brainstem/cerebellum	18.4	12.4	17.4	17.8	36.7	10.0	9.1	17.7	16.9	
Subcortical	31.0	40.2	30.4	13.3	23.3	46.7	45.5	11.8	31.7	
Brainstem + subcortical	6.9	4.1	5.8	4.4	3.3	6.7	18.2	0.0	5.8	
Lobar (includes cortex)	37.9	37.1	40.6	53.3	33.3	33.3	22.7	58.8	39.3	
Unknown	5.8	6.2	5.8	11.1	3.3	3.3	4.6	11.8	6.3	
Mean admission total FIM score	64.4	61.7	56.4	52.7	50.2	51.5	49.3	45.7	57.4	<.001*
Mean admission motor FIM score	44.5	42.2	37.5	35.0	34.5	34.1	33.9	28.9	38.9	
Mean admission cognitive FIM score	19.9	19.5	19.0	17.6	15.6	17.7	15.4	17.4	18.5	.001*
Mean admission CSI	18.5	17.7	20.4	23.1	24.0	25.9	24.0	29.1	20.9	.002*
Prerehabilitation health care										
Mean time from stroke onset to rehabilitation (d)	12.1	14.1	14.6	16.4	17.9	8.3	13.0	10.6	13.7	.475*
Mean acute hospital LOS preceding rehabilitation (d)	12.2	15.3	18.9	20.6	23.6	26.8	30.6	34.7	19.0	<.001*

Abbreviation: CSI, Comprehensive Severity Index.
*Analysis of variance (ANOVA).
†Chi-square test.

patient characteristics (including admission FIM score, severity of illness, and demographic factors), was 40% for moderate strokes and 45% for severe strokes. When total time per day spent on physical therapy (PT), occupational therapy (OT), and SLP was added, there was no increase in variation explained for discharge FIM, consistent with previous findings by Bode et al.[23] However, when time per day spent in specific PT, OT, and SLP activities was added, the amount of variation explained increased to 52% for moderate strokes and 68% for severe strokes, adding 12% and 23% explanation of variation, respectively, in discharge FIM scores.

Functional performance for each study patient at admission to and discharge from inpatient rehabilitation was obtained via retrospective chart review using the study site's reporting of the FIM instrument.[24] We assumed that all clinicians providing FIM data within IRFs as part of standard practice were FIM credentialed; no additional documentation of FIM elements was performed for project purposes.

Data Analysis

Descriptive statistics were used to describe study variables. Patient, process, and outcome variables were compared using chi-square tests for categoric data and analysis of variance tests for continuous data. Correlation analyses were used to detect multicollinearity between predictor variables. Identified predictor variables and severity of illness were combined in logistic regression analyses to determine their concurrent effects on outcomes.

For logistic regression, a stepwise selection procedure with a significance level of .10 allowed independent variables to enter and leave the model. The importance of each variable in affecting an outcome was determined by the Wald chi-square statistic and odds ratio with 95% confidence interval. Discrimination c statistics (area under receiver operating characteristic curves) were used to evaluate how well each model distinguished, for example, patients who were successful in reaching the specified FIM level at discharge from patients who were not successful.

To examine the relation between SLP activities and outcomes, we used changes in FIM elements of auditory comprehension and verbal expression. These items were selected for analysis because they most directly describe the communication status of a patient and are measured independently of cognitive components that are frequently decreased in poststroke patients (ie, memory, problem solving, social interaction). Although SLP addresses these cognitive

Table 2: SLP Process Variables: Patients Without Aphasia Diagnosis and With Admission FIM Comprehension Level of 1 Through 5 (n=397)

Variables	1 Block (n=87)	2 Blocks (n=97)	3 Blocks (n=69)	4 Blocks (n=45)	5 Blocks (n=30)	6 Blocks (n=30)	7 Blocks (n=22)	8 Blocks (n=17)	All (n=397)
Mean LOS	12.2	15.3	18.9	20.6	23.6	26.8	30.6	34.7	19.0
Mean SLP intensity									
No. of days of therapy during rehab	5.0	8.1	11.0	13.5	16.3	18.6	22.0	24.8	11.4
No. of sessions during rehab	6.2	10.9	15.3	19.3	24.8	28.1	33.5	39.7	16.4
No. of minutes during rehab	214	376	556	724	914	1079	1304	1439	602
Mean SLP activities (% time)									
Swallowing + face/neck mobility	19.5	16.5	19.3	24.1	24.9	19.8	23.6	25.4	20.2
Speech/intelligibility	7.2	7.6	9.2	8.8	5.4	7.6	11.2	7.4	8.0
Voice	1.7	1.5	0.7	1.4	1.7	1.7	3.5	2.0	1.6
Verbal expression	12.5	11.8	8.9	8.4	9.7	5.8	10.4	7.8	10.2
Alternative/nonverbal expression	0.3	0.1	0.6	0.0	0.8	0.2	1.0	0.0	0.3
Written expression	2.6	3.4	2.9	1.4	3.0	1.7	1.1	3.5	2.6
Auditory comprehension	8.8	7.6	8.0	8.2	8.4	7.2	6.7	4.9	7.9
Reading comprehension	5.6	8.2	6.7	5.8	6.4	7.3	6.2	7.8	6.8
Problem solving/reasoning	16.7	19.1	17.8	17.7	18.8	24.9	15.6	19.5	18.4
Orientation	5.2	3.7	5.6	4.7	4.2	2.6	4.3	4.1	4.5
Attention	5.2	5.1	5.7	7.2	6.7	7.7	9.5	11.1	6.3
Memory	8.5	9.0	7.9	9.0	5.2	8.5	4.1	3.7	7.9
Pragmatics	0.1	0.9	1.0	0.4	1.1	0.6	0.5	0.1	0.6
Executive functioning skills	4.7	3.4	3.2	1.8	1.3	8.7	0.8	1.8	2.9
Prefunctional + activities not related to SLP skills	1.5	1.8	1.0	0.8	0.3	0.4	0.4	0.4	1.1

NOTE. Each patient in 1 block only, for example, patient with 20 total hours of SLP appears in block 6 only.

and linguistic areas through treatment, the variables of auditory comprehension and verbal expression best represent the functional ability of the patient to interact with the environment. To define success, we identified 2 markers for low-level patients and a different pair of markers for mid-level patients (one for improvement in comprehension, one for improvement in expression).

The first analysis defined success for low-level patients (admission FIM levels 1–3 for comprehension alone and then combined levels 1–3 for expression) as the discharge comprehension FIM score increasing by 2 or more levels; a second analysis defined success as the discharge expression FIM score increasing to level 4 (minimal assistance) or higher.

Mid-level patients (admission FIM levels 4–5 for comprehension alone and then combined with expression) were considered successful if the discharge FIM comprehension score increased to level 6 or higher and, in a second analysis, the discharge FIM expression score increased to level 6 or higher.

For purposes of interpreting and discussing the data, we classified SLP activities into categories of cognitively and linguistically simple, mid-level cognitively and linguistically complex, and high-level cognitively and linguistically complex based on a clinical consensus of the average complexity of activities and demands on a patient within a given activity. Cognitively and linguistically simple activities were those that addressed the most basic skill areas or were primarily motor based: swallowing, speech intelligibility, voice, alternative and nonverbal expression, orientation, and attention. The activity of "face/neck mobility" was combined with "swallowing" during analysis because of a low number of recordings for this category. Mid-level cognitively and linguistically complex activities were those that involved greater demands of the patient or were more abstract: verbal and written expression, auditory and reading comprehension, memory, and pragmatics. High-level cognitively and linguistically complex activities involved activities with the most multiple components: executive functioning skills, problem solving, and reasoning. Although patients do participate in complex tasks within activities that are considered simple (eg, divided attention tasks in community settings) and simple tasks within activities that are considered complex (eg, engaging problem solving by locating and using the nursing call bell to request assistance), we believed that this delineation best described the average usage of these activities by clinicians on a day-to-day basis.

RESULTS

This sample of 397 communicators with low- to mid-level functioning received a mean of 16.4 SLP therapy sessions over the course of their rehabilitation stays. These sessions were conducted over an average of 11.4 days and consumed an average of 602 minutes (table 2). Naturally, patients with 8 three-hour blocks of therapy received much more SLP therapy than patients with 1 to 3 blocks. Thus, for continued analyses, we included only time in each activity performed during the first block (3h) of SLP treatment time, regardless of the total number of SLP blocks of time a patient received over the whole rehabilitation stay (table 3). This ensured that patients were functioning at the identified communication level (as measured by admission FIM) at the time of participation in SLP activities. We did not measure incremental increases in FIM score during the rehabilitation stay, and therefore, it was important to reduce the confounding effect of function naturally improving over the course of

Table 3: SLP Process Variables: Patients Without Aphasia Diagnosis and With Admission FIM Comprehension Level of 1 Through 5 (n=397)

Variables*	1 Block (n=87)	2 Blocks (n=97) Time in 1st block	3 Blocks (n=69) Time in 1st block	4 Blocks (n=45) Time in 1st block	5 Blocks (n=30) Time in 1st block	6 Blocks (n=30) Time in 1st block	7 Blocks (n=22) Time in 1st block	8 Blocks (n=17) Time in 1st block	Mean % Time in All 1st Blocks
Swallowing + face/neck mobility	28.9	25.1	22.2	49.9	36.6	24.4	26.4	46.6	30.7
	15.1	22.4	29.4	23.8	39.4	44.8	30.5	35.3	25.3
Speech/intelligibility	2.6	3.4	7.5	3.4	3.7	4.4	3.9	6.1	4.1
	10.2	8.6	12.0	9.6	7.2	9.1	11.2	3.7	9.7
Voice	0.2	0.9	0.1	1.7	0.2	1.4	0.3	0.0	0.6
	2.3	1.8	0.6	2.3	2.9	0.2	0.0	4.0	1.7
Verbal expression	10.2	14.0	7.3	12.0	7.9	9.6	10.0	11.0	10.8
	13.2	6.0	8.1	4.4	7.1	1.6	10.5	0.1	7.7
Alternative/nonverbal expression	0.5	0.0	1.1	0.0	0.9	0.5	0.0	0.9	0.5
	0.3	0.2	0.0	0.0	0.0	0.0	1.9	0.0	0.2
Written expression	1.4	2.6	4.7	0.7	4.3	3.3	1.4	1.2	2.6
	2.7	2.0	1.9	1.4	0.8	2.5	0.0	3.3	2.0
Auditory comprehension	10.1	11.0	10.0	6.2	11.0	14.0	12.0	6.8	10.4
	8.1	5.7	6.7	9.2	6.0	0.3	8.7	3.7	6.6
Reading comprehension	3.7	8.4	9.0	4.4	7.0	2.9	4.2	2.8	5.9
	6.0	7.6	6.2	8.5	4.2	4.6	4.0	10.4	6.6
Problem solving/reasoning	12.8	7.2	10.0	3.8	12.6	15.0	3.0	4.7	9.3
	15.9	19.9	10.0	17.1	14.4	14.3	13.9	18.1	15.7
Orientation	9.3	7.9	9.6	6.7	5.3	5.2	8.4	6.9	7.7
	1.4	1.4	3.6	2.8	4.2	7.6	1.0	1.9	2.5
Attention	3.9	7.0	7.2	3.9	3.3	7.4	12.0	6.9	6.0
	6.1	2.5	3.1	7.4	6.5	1.4	3.3	19.0	4.7
Memory	11.3	6.7	4.2	5.9	1.5	4.5	4.1	5.2	6.1
	7.5	8.6	7.6	7.5	3.4	8.7	0.8	0.6	7.1
Pragmatics	0.1	0.2	0.3	0.6	0.6	0.2	1.0	0.0	0.3
	0.0	1.1	1.4	0.0	1.5	0.8	0.0	0.0	0.7
Executive functioning skills	2.9	1.7	0.8	0.0	1.9	0.0	0.0	0.0	1.3
	6.1	4.4	4.9	3.8	2.5	0.0	0.0	0.0	4.1
Prefunctional + activities not related to SLP skills	2.0	1.2	0.3	0.3	0.0	1.5	3.2	0.0	1.1
	1.2	4.2	2.7	2.4	0.0	0.0	5.2	0.0	2.4

NOTE. Each patient in 1 block only: for example, patient with 20 total hours of SLP appears in block 6 only. Percentage of time spent in the first 3-hour block only is displayed.
*SLP activities mean percentage of time. First line of each variable is for patients with admission FIM comprehension level 1–3 (n=176). Second line of each variable is for patients with admission FIM comprehension level 4–5 (n=221).

rehabilitation. Had we examined time in activities later in the stay, the outcomes at discharge could have been confounded with the natural recovery process or performance of other activities. In using the first block, we hypothesized that patients would not have had time to improve in their functioning, as they might have if we had included all blocks (2–8) in regression analyses.

For these communicators with low- to mid-level functioning, the total and cognitive FIM scores increased by means of 27.7 and 5.4, respectively, from admission to discharge. Changes in FIM scores from admission to discharge and discharge destination as related to number of SLP therapy blocks for this patient sample are presented in table 4.

Logistic Regression

We allowed many variables (eg, demographics, admission functioning level, medical severity of illness, stroke locations; see table 1) to enter stepwise selection procedures to identify variables associated with greater or less likelihood of patients achieving our defined success outcomes. Because admission FIM motor and cognitive scores aggregate functional information across different activities, 2 patients with very different disabilities may have an identical score composed of higher and lower levels from different areas. This means that use of motor and cognitive scores may not adequately control for patients' starting disability levels. To overcome this concern, we performed an additional set of regression models allowing individual motor and cognitive components of the FIM to enter instead of admission FIM motor and cognitive scores. In addition, we allowed number of minutes during the first therapy block for each SLP activity (eg, swallowing, orientation, problem solving) to enter the model. Another variable allowed to enter was the FIM discharge bladder level, because bladder function and level of continence can be considered a surrogate indicator for overall cognitive-communication functioning level. Patients with lower-level cognitive and communication function typically have lower awareness of the need to void and/or the ability to obtain necessary help for toileting to maintain continence. Bladder function seems to be an indicator of potential for recovery, a difference between those who succeed and those who

Table 4: PSROP SLP Outcome Variables: Patients Without Aphasia Diagnosis and With Admission FIM Comprehension of Levels 1 Through 5 (n=397)

Variables	1 Block (n=87)	2 Blocks (n=97)	3 Blocks (n=69)	4 Blocks (n=45)	5 Blocks (n=30)	6 Blocks (n=30)	7 Blocks (n=22)	8 Blocks (n=17)	Total (n=397)	P
FIM										
Mean discharge total FIM score	88.6	86.6	85.1	81.9	78.8	86.0	76.7	83.3	84.9	.192*
Mean discharge FIM bladder component score	5.3	5.1	4.9	4.8	4.9	5.2	4.4	4.5	5.0	.577*
Mean increase in total FIM score (discharge − admission)	24.3	25.5	28.5	29.0	28.3	34.1	27.5	38.6	27.7	.003*
Mean discharge motor FIM score	63.9	62.2	60.6	58.9	57.6	61.3	55.0	57.8	60.9	.346*
Mean increase in motor FIM score (discharge − admission)	19.6	20.6	23.0	24.0	23.1	27.0	21.1	30.1	22.3	.023*
Mean discharge cognitive FIM score	24.5	24.4	24.5	22.7	20.9	24.7	21.8	25.5	23.9	.035*
Mean increase in cognitive FIM score (discharge − admission)	4.6	4.9	5.5	5.1	5.3	7.0	6.4	8.1	5.4	.015*
Discharge destination (%)										.143†
Inpatient institutional discharge	18.4	17.5	21.7	26.7	40.0	16.7	31.8	11.8	21.7	
Community discharge including home	81.6	82.6	78.3	73.3	60.0	83.3	68.2	88.2	78.3	
Home	79.3	80.4	69.6	73.3	60.0	80.0	68.2	88.2	75.6	.203†
Admission FIM comprehension level 1–3 (n=176)										
Increase in comprehensive component score of ≥2 levels from levels 1–3 (% patients)	40.0	45.0	56.0	47.4	30.0	75.0	63.6	80.0	50.0	.054†
Increase in expression component score from level 1–3 to ≥level 4 (% patients)	54.3	67.5	64.0	57.9	65.0	87.5	36.4	70.0	63.1	.223†
Admission FIM comprehension level 4–5 (n=221)										
Increase in comprehensive component score from level 4–5 to ≥6 (% patients)	59.6	59.7	52.3	38.5	30.0	42.9	54.6	71.4	53.4	.350†
Increase in expression component score from level 4–5 to ≥level 6 (% patients)	53.9	63.2	54.6	50.0	40.0	50.0	18.2	57.1	53.4	.280†

*ANOVA.
†Chi-square test.

do not. The level of continence has been established as a compelling factor in determining discharge disposition.[25]

Sample 1

Logistic regression analyses predicting increase in FIM comprehension and expression scores for communicators with low-level function are presented in table 5.

In sample 1a (176 patients without aphasia diagnosis, with admission FIM comprehension levels 1–3), 50% (88 patients) achieved success. Even after controlling for multiple patient characteristics, creating otherwise matched groups, several mid-level and complex SLP activities were associated with greater likelihood of success in these low-level patients, including more time spent in problem-solving and executive functioning activities in the first 3-hour block. Several SLP activities were associated with less likelihood of success: more time spent in orientation, verbal expression, and written expression activities. Low-level bladder functioning by the time of discharge was also associated with less likelihood of success (c=.812). Bladder function appears to covary with improvement in communication-cognitive function.

When we removed admission FIM motor and cognitive scores and allowed the motor and cognitive components of FIM to enter individually, the model remained the same, including for SLP activities associated with greater or less likelihood of success.

For the subset of 141 patients with FIM admission levels 1 through 3 for both comprehension and expression (sample 1b) and with success defined as reaching FIM expression level 4 or higher by discharge (77 [55%] patients successful), similar results were found: more time spent doing a cognitively and linguistically complex SLP activity (problem solving) during the first 3-hour block was associated with greater likelihood of success, as was high bladder functioning at discharge. Mid-level and simple SLP activities (eg, reading comprehension, memory) were associated with less likelihood of success (c=.849).

When we removed admission FIM motor and cognitive scores and allowed the motor and cognitive components of FIM to enter individually, similar SLP activities were associated with greater or less likelihood of success (c=.886).

Sample 2

Logistic regression analyses predicting increase in FIM comprehension and expression for communicators with mid-level functioning are presented in table 6.

Table 5: Logistic Regression Analyses Predicting Increase in FIM Comprehension and Expression for Communicators With Low-Level Functioning Without a Diagnosis of Aphasia (Sample 1)

Sample 1a: 176 Patients, Admission FIM Comprehension Levels 1–3					Sample 1b: 141 Patients, Admission FIM Comprehension Levels 1–3 and Admission FIM Expression Levels 1–3				
Variables	Parameter Estimate	Wald χ^2 Test	*P*	Odds Ratio	Variables	Parameter Estimate	Wald χ^2 Test	*P*	Odds Ratio
Outcome = increase of ≥2 FIM comprehension levels from admission to discharge (88 patients/50% success) (*c*=.805)					Outcome = increase in FIM expression from levels 1–3 at admission to ≥ level 4 at discharge (77 patients/54.6% success) (c=.849)				
Successful variables					Successful variables				
SLP activity problem solving	0.03	6.01	.014	NA	SLP activity problem solving	0.07	13.75	<.001	NA
SLP activity executive functioning	0.08	6.62	.010	NA	LOS	0.10	13.63	<.001	NA
LOS	0.11	20.87	<.001	NA	Hemorrhagic stroke	1.29	6.72	.010	1.4–9.6
Unsuccessful variables					Higher admission FIM cognitive score	0.20	10.94	.001	NA
SLP activity verbal expression	−0.02	4.68	.030	NA	FIM discharge bladder level 1-3	2.11	18.21	<.001	3.1–21.7
SLP activity written expression	−0.05	4.76	.029	NA	Unsuccessful variables				
FIM discharge bladder level 1-3	−1.83	17.89	<.001	.07–.36	SLP activity reading comprehension	−0.05	5.03	.025	NA
Female	−1.02	7.11	.008	.15–.71					
Brain location brainstem/cerebral	−1.86	10.89	.001	.05–.44					
If we remove admission motor and cognitive scores and allow motor and cognitive components to enter, 88 patients/50% success (*c*=.805)					If remove admission motor and cognitive scores and allow motor and cognitive components to enter (77 patients/55% success) (*c*=.886)				
Same as above					Successful variables				
					SLP activity problem solving	0.06	6.45	.011	NA
					SLP activity executive functioning	0.13	4.55	.033	NA
					LOS	0.11	14.42	<.001	NA
					Higher admission FIM component expression	1.41	14.29	<.001	NA
					Unsuccessful variables				
					SLP activity reading compression	−0.05	6.14	.013	NA
					FIM discharge bladder level 1–3	−2.90	21.36	<.001	.02–.19
					FIM discharge bladder level 4–5	−1.29	4.45	.035	.08–.91
					Female	−1.17	5.46	.020	.12–.83

NOTE. Variables allowed to enter the model include admission FIM motor and cognitive scores; admission CSI score; increase in severity; net medical improvement; side of stroke: left, right, bilateral; hemorrhagic stroke; location in brain: lobar, subcortical, brainstem/cerebral, subcortical; diabetes diagnosis; female; race: black, white, other; hospital inpatient stay >20 days; admission FIM bladder level: 1–3, 4–5, 6–7; SLP activities in first 3-hour block: swallowing, speech/intelligibility, voice, verbal expression, alternative nonverbal expression, writing expression, auditory comprehension, reading comprehension, problem solving/reasoning, orientation, attention, memory, pragmatics, executive functioning, nonfunctional. Reference variables were brain side unknown, brain location unknown, and race unknown.
Abbreviation: NA, not applicable.

When we repeated regression analyses with sample 2a (221 patients without an aphasia diagnosis and with admission FIM comprehension scores of 4 and 5), again we found that more time spent performing mid-level and simple SLP activities (auditory comprehension) in the first 3-hour block of SLP time was associated with less likelihood of success (discharge FIM comprehension level ≥6) and more time spent in the complex activity of problem solving was associated with greater likelihood of success (*c*=.788). Removing admission FIM motor and cognitive scores and allowing the motor and cognitive components of FIM to enter individually produced similar results, including the SLP activity of problem solving associated with greater likelihood of success (*c*=.844).

When controlling for admission expression level in addition to comprehension (sample 2b), more time spent in problem-solving activities again was associated with greater likelihood of success, whereas more time spent in verbal expression was associated with less likelihood of success (*c*=.808). Similar results were found when we removed admission FIM motor and cognitive scores and allowed the motor and cognitive components of FIM to enter individually (*c*=.872).

DISCUSSION

For most patients without an aphasia diagnosis, PSROP data indicate that use of activities involving problem solving is associated with greater likelihood of improved outcomes in verbal expression and auditory comprehension. These results indicate that perhaps problem-solving activities, which by their nature involve critical thinking, mental flexibility, integration of multiple components of information, and mental manipulation, generally lead to better auditory processing and inferencing skills, as measured via auditory comprehension FIM data, as well as to increased capacity for discourse, as measured via verbal expression FIM data. Taking a top-down therapeutic approach naturally may recruit a greater number of cognitive and linguistic skills (ie, error detection, revision/repair, self-

Table 6: Logistic Regression Analyses Predicting Increase in Comprehension and Expression for Mid-Level Functional Communicators: Patients Without Aphasia Diagnosis (Sample 2)

Sample 2a: 221 Patients With Admission FIM Comprehension Levels 4–5					Sample 2b: 144 Patients With Admission FIM Comprehension Levels 4–5 and Admission FIM Expression Levels 4–5				
Variables	Parameter Estimate	Wald χ^2 Test	*P*	Odds Ratio	Variables	Parameter Estimate	Wald χ^2 Test	*P*	Odds Ratio
Outcome = increase in FIM comprehension level from 4–5 at admission to ≥6 at discharge (114 patients/52% success) (*c*=.788)					Outcome = increase in FIM expression from levels 4–5 at admission to ≥ level 6 at discharge (75 patients/52% success) (*c*=.824)				
Successful variables					Successful variables				
SLP activity problem solving	0.01	2.80	.094	NA	SLP activity problem solving	0.03	7.90	.005	NA
Higher admission cognitive score	0.16	13.70	<.001	NA	Race white	0.99	4.31	.038	1.1–6.9
LOS	0.06	7.80	.005	NA	Higher admission FIM cognitive score	0.22	10.54	.001	NA
Unsuccessful variables					FIM discharge bladder level 6–7	1.45	7.68	.006	1.5–11.9
SLP activity auditory comprehension	−0.05	12.28	<.001	NA	Unsuccessful variables				
Higher admission CSI score	−0.03	3.83	.050	NA	SLP activity verbal expression	−0.02	5.28	.022	NA
FIM discharge bladder level 1–3	−1.17	5.36	.021	.12–.84	Hemorrhagic stroke	−1.36	6.13	.013	.09–.75
					Higher admission CSI score	−0.07	7.95	.005	NA
					Higher admission FIM motor score	−0.08	12.35	<.001	NA
If remove admission motor and cognitive scores and allow motor and cognitive components to enter (116 patients/53% success) (*c*=.844)					If remove admission motor and cognitive scores and allow motor and cognitive components to enter (76 patients/53% success) (*c*=.867)				
Successful variables					Successful variables				
SLP activity problem solving	0.02	5.12	.024	NA	SLP activity problem solving	0.03	4.89	.027	NA
Higher admission FIM component memory	0.46	12.51	<.001	NA	FIM discharge bladder level 6–7	1.57	8.91	.003	1.7–13.4
Higher admission FIM component comprehension	1.75	24.06	<.001	NA	Higher admission FIM component expression	2.39	22.33	<.001	NA
LOS	0.06	7.53	.006	NA	LOS	0.08	6.50	.011	NA
Unsuccessful variables					Unsuccessful variables				
SLP activity auditory comprehension	−0.04	6.45	.011	NA	Higher admission FIM component toilet transfer	−0.56	5.38	.020	NA
Higher admission CSI score	−0.03	5.36	.021	NA	Race other	−1.45	3.91	.048	.05–.99
					Higher admission CSI score	0.08	8.87	.003	NA
					Hemorrhagic stroke	−1.72	7.82	.005	.05–.60

NOTE. Variables allowed to enter the model include admission FIM motor and cognitive scores; admission CSI score; increase in severity; net medical improvement; side of stroke: left, right, bilateral; hemorrhagic stroke; location in brain: lobar, subcortical, brainstem/cerebral, subcortical; diabetes diagnosis; female; race: black, white, other; hospital inpatient stay >20 days; admission FIM bladder level: 1–3, 4–5, 6–7; SLP activities in first 3-hour block: swallowing, speech/intelligibility, voice, verbal expression, alternative nonverbal expression, writing expression, auditory comprehension, reading comprehension, problem solving/reasoning, orientation, attention, memory, pragmatics, executive functioning, nonfunctional. Reference variables were brain side unknown, brain location unknown, and race unknown.

regulation) that trickle down into expanded and strengthened components of functional language (ie, inferencing, expanded semantic and syntactic constructs). These areas are often decreased in poststroke patients without a diagnosis of aphasia[8] and have at their roots a breakdown in the integration of information versus true comprehension and formulation deficits, as in those with aphasia. Clinicians did report working on individual activities of auditory comprehension and verbal expression in isolation with patients without a diagnosis of aphasia; however, the data suggest that addressing these target areas in an integrated manner results in more improvement than working on each deficit area in isolation.

The strengths of this study are many, because the breadth of the data collected and large number of subjects allowed for the formulation of homogenous groups for comparison. It also provided a comprehensive look at what patients actually experience at the hands of SLPs in a natural setting. The weaknesses of the study, however, are related to the strengths, in that multiple objective and subjective choices about how to carve out homogeneous groups were required. Additionally, despite the best efforts of clinical leaders at each site to promote accuracy and consistency in use of the intervention documentation forms, the reality of busy clinicians completing additional paperwork per treatment session may have resulted in quick decision making about the true nature of activities and interventions performed. The documentation form did not allow for recording the context in which an activity was performed, which also may have an impact on the functional outcome for a patient. For example, if a clinician addresses problem solving by using real-life materials such as bank checks or newspaper coupons, the patient's performance, involvement, and benefit from the task may be different than the same goals targeted in a hypothetical, fabricated context. However, despite these limitations, significant variation in outcomes

was found associated with differences in time spent per day in specific SLP activities.

The clinical implications of these results are potentially great, because they indicate that offering mid- to high-level cognitively and linguistically complex activities earlier in a patient's episode of care is more likely to result in favorable outcomes. Generally, clinical consensus in SLP practice is to select an activity and intervention strategy at just a notch in complexity above the current functional performance of the patient, gradually increasing complexity as the patient progresses to maintain a relatively high patient success rate.[26] Initiating complex tasks within the first 3 hours of treatment seems counterintuitive at first. However, results of this study indicate that doing so may increase significantly the patient's likelihood of advancing their independence in functional communication skills. Additionally, current practice techniques tend to match an activity with a category of impairment—that is, if a patient has decreased auditory comprehension, a clinician will select activities and use interventions directly targeting auditory comprehension. Results of this study indicate that more time spent in tasks of analysis and synthesis of information improves both verbal expression and auditory comprehension, although neither was specifically addressed via those tasks. Results also indicate that collaboration between SLP and OT early on in a patient's rehabilitative stay potentially could improve other FIM areas such as continence. For example, accessing and using a call bell system to convey the need for toileting activates a patient's simple cognitive-linguistic skills (ie, initiation of functional problem solving and of conveying a basic need) as a means to enhance both auditory comprehension and verbal or nonverbal communication. Addressing these skills provides the SLP with a starting point to tap into each patient's cognitive and linguistic skills using meaningful and purposeful activities that naturally increase functional communication outcomes.

It appears that challenging a patient early in the rehabilitation stay and addressing multicomponent integration and mental manipulation tasks potentially has far-reaching effects. Asking patients who present with low linguistic ability to perform more complex cognitive and linguistic tasks may require more clinician cueing and assistance but appears to be associated with more efficient generalization of skills, as indicated by functional performance at discharge.

Future research implications of this study's results include using these findings to guide controlled trials of trends that rose above the noise of this large data set. Results could be correlated with standardized test measures of speech and language performance, such as the auditory comprehension and verbal expression subtests of the Western Aphasia Battery.[27] Further analyses of PSROP data could ask different questions about current practice principles. Examining specific interventions used within each complex SLP activity, as well as specific activities and interventions used with patients with a diagnosis of aphasia, time spent in initial and interim evaluation, clinical practice variation across specific clinicians and treatment sites, and use of treatment groups will further our understanding of these current results.

CONCLUSIONS

For every practicing clinician who works with poststroke patients in inpatient rehabilitation there is a unique set of guiding principles, intervention techniques, and management styles learned from a body of literature, overt teaching and mentoring, experience, and pure instinct. For every stroke survivor who participates in an inpatient rehabilitation program there is a unique set of functional goals, comorbidities, learning style, and attitude toward recovery.

Historically, SLP treatment plans have been driven by individual clinician rationale; however, given the rather surprising evidence drawn from these data regarding the complexity of activities SLPs offer stroke rehabilitation patients early in their treatment, there is a clear need for further investigation of factors that drive clinician decision making, as well as patient variables that may impact the functional success or failure of achievement in a targeted skill area. The primary objective of this article was to test the hypothesis that use of cognitively and linguistically complex SLP activities early in a patient's stay may result in better outcomes, regardless of the patient's functional communication severity level on admission, but clearly further examination is both necessary and welcome. Future data analyses will provide a more detailed description of specific interventions and activities used in acute stroke rehabilitation with an eye toward determining best practices that will guide the type of activities, timing, frequency, duration, and interventions that make up the provision of SLP services with poststroke patients during inpatient rehabilitation.

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APPENDIX 1: FIM SCORING LEVELS FOR COGNITIVE COMPONENTS: COMPREHENSION AND EXPRESSION

Comprehension

Includes understanding of either auditory or visual communication (eg, writing, sign language, gestures). Records the more usual modality (auditory, visual, or both).

7 Complete independence: subject understands directions and conversation that are complex or abstract; understands either spoken or written language.
6 Modified independence: in most situations, subject understands complex or abstract directions and conversation readily or with only mild difficulty. No prompting is needed. May require a hearing aid or other assistive device or extra time to understand the information.
5 Standby prompting: subject understands directions and conversation about basic daily needs more than 90% of the time. Requires prompting (slowed speak, use of repetition, stressing of particular words or phrases, pauses, visual or gestural cues) less than 10% of the time.
4 Minimal prompting: subject understands directions and conversation about basic daily needs 75% to 90% of the time.
3 Moderate prompting: subject understands directions and conversation about basic daily needs 50% to 74% of the time.
2 Maximal prompting: subject understands directions and conversation about basic daily needs 25% to 49% of the time. Understands only simple, commonly used expressions or gestures. Requires prompting more than half the time.
1 Total assistance: subject understands directions and conversation about basic daily needs less than 25% of the time, does not understand simple, commonly used spoken expressions or gestures, or does not respond appropriately or consistently despite prompting.

NOTE: Comprehension of complex or abstract information includes but is not limited to understanding current events appearing in television programs or newspaper articles or abstract information on subjects such as religion, humor, math, or finances used in daily living. This may also include information given during group conversation. Information about daily needs refers to conversation, directions, questions, or statements related to a subject's need for nutrition, fluids, elimination, hygiene, or sleep.

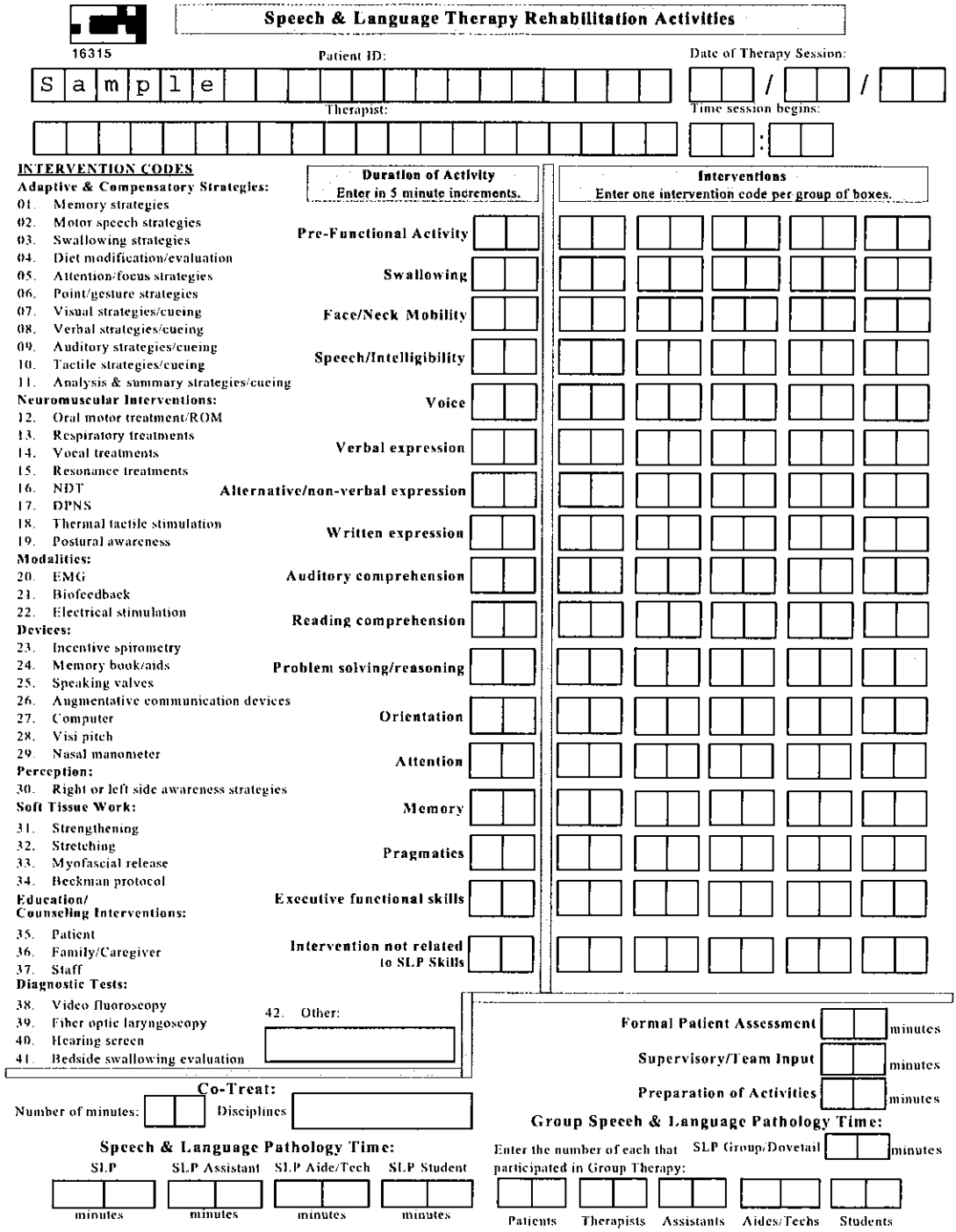
Expression

Includes clear vocal or nonvocal expression of language. This item includes either intelligible speech or clear expression of language using writing or communication device. The item records the more prevalent modality (vocal, nonvocal, or both).

7 Complete independence: subject expresses complex or abstract ideas clearly and fluently, not necessarily in Englisb.
6 Modified independent: in most situations, subject expresses complex or abstract ideas relatively clearly or with only mild difficulty. No prompting is needed. May require an augmentative communication device or system.
5 Standby prompting: subject expresses basic daily needs and ideas more than 90% of the time. Requires prompting (eg, frequent repetition) less than 10% of the time to be understood.
4 Minimal prompting: subject expresses basic daily needs and ideas 75% to 90% of the time.
3 Moderate prompting: subject expresses basic daily needs and ideas 50% to 74% of the time.
2 Maximal prompting: subject expresses basic daily needs and ideas 25% to 49% of the time. Uses only single words or gestures. Needs prompting more than half the time.
1 Total assistance: subject expresses basic daily needs and ideas less than 25% of the time or does not express basic needs appropriately or consistently despite prompting.

NOTE: Examples of complex or abstract ideas include but are not limited to discussing current events, religion, or relationships with others. Expression of basic needs and ideas refers to a subject's ability to communicate about necessary daily activities such as nutrition, fluids, elimination, hygiene, and sleep.

APPENDIX 2: SLP INTERVENTION DOCUMENTATION FORM*



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Abbreviations: DPNS, direct pharyngeal nerve stimulation; EMG, electromyography; NDT, neurodevelopmental technique; ROM, range of motion.
*Definition of terms available on request.

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ORIGINAL ARTICLE

An Exploration of Central Nervous System Medication Use and Outcomes in Stroke Rehabilitation

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ABSTRACT. Conroy B, Zorowitz R, Horn SD, Ryser DK, Teraoka J, Smout RJ. An exploration of central nervous system medication use and outcomes in stroke rehabilitation. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S73-81.

Objective: To study associations between neurobehavioral impairments, use of neurotropic medications, and outcomes for inpatient stroke rehabilitation, controlling for a variety of confounding variables.

Design: Observational cohort study of poststroke rehabilitation.

Setting: Six inpatient rehabilitation hospitals in the United States.

Participants: Patients with moderate or severe strokes (N=919).

Interventions: Not applicable.

Main Outcome Measures: Discharge disposition, FIM score change, and rehabilitation length of stay (LOS).

Results: Neurobehavioral impairments and use of many medications, including first-generation selective serotonin reuptake inhibitors, older traditional antipsychotic medications, and anti-Parkinsonian neurostimulants, have a statistical association with poorer outcomes, whereas use of the atypical antipsychotic medications has a positive association with improvement in motor FIM scores. Counterintuitively, use of opioid analgesics is associated with a larger motor FIM score change but not an increase in LOS or reduced percentage of discharge to community. There was significant variation in use of neurotropic medications among the 6 study sites during inpatient stroke rehabilitation.

Conclusions: There are many opportunities to enhance a stroke survivor's ability to benefit from acute inpatient stroke rehabilitation through improved understanding of associations of neurotropic medications with outcomes for different patient groups.

Key Words: Antipsychotic agents; Clinical practice variations; Rehabilitation; Stroke; Treatment outcome.

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ANNUAL MEDICARE EXPENDITURES for hospital-based rehabilitation in the United States reached $5.9 billion in 2004.[1,2] Stroke, a leading cause of adult onset disability, is the second leading cause for admission to inpatient rehabilitation and is associated with high costs and intensive utilization of rehabilitation resources.[3-5] Neurologic and behavioral impairments, such as delirium, dementia, agitation, anxiety, apathy, psychomotor slowing, impulsivity, and depression, are common in stroke survivors and can have a negative association with participation in therapy, length of stay (LOS), discharge disposition, resultant functional outcome, and ultimate quality of life.[6-15]

Stroke-related depression literature[6-15] states that depression is probably the most common neurologic and behavioral impairment disorder after stroke, that it occurs in 30% to 50% of stroke patients,[8] and that depressive symptoms and pharmacologic treatments extend well beyond the first few weeks after stroke.[7-15] Importantly, there are studies that have found that major depression may not become diagnosable until several months after stroke onset.[16] In contrast, during the immediate poststroke period—when patients are most likely to undergo intensive rehabilitation therapy—other mood and behavior disturbances are more prevalent than a major depressive disorder, but few studies exist on this subject.[6] Examples of neurologic and behavioral impairments that can occur soon after the onset of a stroke and can interfere with rehabilitation care include apathy, agitation, anxiety, insomnia, psychosis, disinhibition, adjustment disorder with depressed mood, delusions, delirium, abulia, pathologic affect, psychomotor slowing, neurogenic and somatic pain, mania, catastrophic reactions, and poststroke fatigue. Several pharmacologic classes of medications (eg, benzodiazepines, antipsychotics, sedatives and hypnotics, anticonvulsants, stimulants, antidepressants) often are used empirically, alone or in combinations, to treat these symptoms. Some of these medications, such as benzodiazepines, the anticonvulsants phenytoin and phenobarbital, and older dopamine receptor antagonists have been associated with poorer upper-extremity motor function and less independence in activities of daily living 84 days poststroke.[17]

According to current literature, the potential benefit of choosing 1 neurotropic medication over another in poststroke mood and behavior disturbances other than depression is particularly unclear, especially in the early poststroke interval (0–4wk after stroke). Do newer neurotropic medications (usually more costly) offer substantial benefits compared with the older, less expensive, and more commonly used medications? Limited access to newer agents because of formulary cost control, as well as a limited number of studies in stroke patients, has impeded the adoption of these medications in clinical practice, thus hindering clinical knowledge of potential benefits.[18] Judicious study of selected neurotropic medications,

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such as olanzapine or quetiapine in poststroke patients with agitation or delirium as opposed to buspirone, benzodiazepines, or haloperidol, has potential to affect outcomes.

Many reasons exist for the paucity of information on effects of neurotropic medications in stroke rehabilitation. There is a concern whether randomized control methods for this type of study are ethically and logistically appropriate in this population. Cognitive and emotional aberrations often affect recruitment into clinical trials because of lack of understanding or altered mental status; randomized controlled trials often exclude these types of impairments. Henon et al[19] found evidence of preexisting dementia in 16% of a series of admissions to their stroke unit. Interactions between the mechanism and anatomic location of the brain lesion in relation to the timing of drug administration, which are not understood completely, may influence a drug's apparent impact on functional recovery.[20]

Analysis of the Post-Stroke Rehabilitation Outcomes Project (PSROP) database uncovered significant variation in the use of medications among 6 U.S. inpatient rehabilitation facilities (IRFs) that cannot be explained by patient differences.[21] This was especially evident in those agents specifically used for their effects on the central nervous system. Physician preferences seemed to be primary determinants of medication choice. Drug formulary restrictions, experience using a particular medication, and other factors may influence physicians' prescriptions.

This study attempts to identify neurotropic medication treatments associated with better outcomes with regard to mood, behavioral, and/or cognitive impairments in stroke rehabilitation. We hypothesize that use of medications that modulate the noradrenergic, dopaminergic, cholinergic, and serotinergic neuroendocrine systems is associated with better outcomes after stroke rehabilitation. A secondary hypothesis is that newer neuroleptic medications are associated with better outcomes compared with older neuroleptic agents. Newer antipsychotic agents purportedly have mechanisms of action that are more effective than older antipsychotics and have a lesser side-effect profile; thus they are better tolerated in patients with stroke and the elderly at risk of iatrogenic disturbances.

METHODS

The methodology governing the full PSROP is discussed in the article by Gassaway et al,[21] which provides a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, and a detailed description of the project's final study group. The methodology is summarized in Maulden et al.[22] The institutional review boards at Boston University and at each participating IRF approved the study.

Patient Variables

PSROP patient variables[21] included age, sex, race, payer, type and location of stroke, admission FIM instrument score, case-mix group (CMG), time from stroke symptom onset to rehabilitation admission, and severity of illness. The Comprehensive Severity Index (CSI), the study's principal severity-of-illness adjuster, is a disease-specific severity assessment system that provides a consistent method for defining levels of severity using over 2200 individual physical findings and laboratory results.[23-27] The CSI was measured separately for admission to rehabilitation (first 24h), discharge from rehabilitation (discharge day), and maximum (the full rehabilitation stay, including admission and discharge periods).

Process Variables (Including Medications)

Details about each neurotropic medication received by study patients were obtained, including drug name, dose, frequency (including as required [PRN] or regular dosing), route of administration, start date and time, and stop date and time. For medications to be included in the PSROP database, the medication needed to be initialized as given on the medication administration record in the patient's chart. PRN medications that were ordered but not given were not included.

We grouped neurotropic medications into categories by consensus of prescribing members of the PSROP clinical team based on similarity of drug content and effects on patients. Drug categories (structured roughly around medication groupings found in ePocrates[28]) used in these analyses are listed in table 1 along with the medications they contain.

Outcome Variables

PSROP outcome variables include rehabilitation LOS, discharge FIM and CSI scores, functional gain as measured by increased FIM score from admission to discharge, increase in severity of illness as measured by increase in CSI from admission to maximum, and discharge disposition.[21]

Patient Subsample With Neurobehavioral Impairment

In the 1161-subject U.S. PSROP sample, we identified patients with indications of neurobehavioral impairment, defined as mood and behavioral disturbances, cognitive impairment, both, or symptoms of neither but presence of certain neurotropic medications indicative of previously treated symptoms. Patients were included in the neurobehavioral impairment group if they met 1 of 3 selection criteria, each of which is analyzed as an independent variable:

1. One or more neurobehavioral impairment diagnoses (eg, major depression, *International Classification of Diseases, 9th Revision, Clinical Modification*,[29] codes 296.2–.3) were documented in their chart.
2. A charted description of a neurobehavioral impairment that included mood or behavioral disturbances and cognitive impairments was documented in their chart. Descriptors for mood or behavioral disturbances included combative, agitated, restless, aggressive, anxious, depressed, emotionally labile, having hallucinations, flat affect, and impulsive. Descriptors for cognitive impairment included decreased safety awareness, impaired or poor judgment or concentration, impaired memory, confused, disoriented, and lethargic.
3. Use of specific neurotropic medications (antidepressants, benzodiazepines, anxiolytics, antipsychotics) without charted descriptions of neurobehavioral impairments or presence of neurobehavioral impairment diagnoses codes. We hypothesized that these patients received medication to continue symptom control.

CMGs were combined into moderate (CMGs 104–107) and severe (CMGs 108–114) stroke patient groups, which were large enough to detect small effects. There were too few patients with mild stroke to be analyzed at this time (CMGs 101–103; n=108).

To include the full inpatient rehabilitation course in these analyses, patients discharged to other acute facilities were excluded (n=134). This left 474 patients in the moderate stroke group and 445 patients in the severe stroke group to allow us to evaluate effectiveness of various medication approaches, including polypharmaceutical combination therapies found to be of benefit in a recent study of long-term-care patients.[18]

Table 1: Descriptions of Medication Categories

Therapeutic Class (No. of Times Therapeutic Class Medication Administered)	Medications Included in Therapeutic Class and No. of Times Each Medication Administered	
Atypical antipsychotics (n=208)	Clozapine	2
	Olanzapine	112
	Quetiapine	51
	Risperidone	43
Traditional antipsychotics (n=47)	Haloperidol	34
	Chlorpromazine	9
	Fluphenazine HCl	1
	Thioridazine	3
Tricyclic antidepressants (n=69)	Amitriptyline	40
	Clomipramine	1
	Desipramine	1
	Doxepin	5
	Imipramine	4
	Nortriptyline	18
Old SSRIs (n=357)	Fluoxetine	59
	Paroxetine	112
	Sertraline	186
New SSRIs (n=167)	Citalopram	126
	Escitalopram	41
Other antidepressants (n=520)	Trazodone	457
	Bupropion	25
	Mirtazepine	23
	Nefazodone	1
	Venlafaxine	14
Analgesic, muscle relaxant (n=197)	Baclofen	76
	Carisoprodol	3
	Cyclobenzaprine	14
	Dantrolene	54
	Metaxalone	4
	Methocarbamol	3
	Tizanidine	43
Anti-Parkinson's medications (n=174)	Bromocriptine	10
	Pergolide	1
	Pramipexole	3
	Carbidopa/levodopa	63
	Amantadine	97
Anxiolytics (n=39)	Buspirone	39
Hypnotics (n=337)	Zalepion	1
	Zolpidem	336
Other neurologics (n=78)	Modafinil	78
Neurostimulants (n=235)	Dexedrine	3
	Methylphenidate	232
Opioid analgesics (n=536)	Codeine	71
	Fentanyl	20
	Hydrocodone	182
	Hydromorphone	8
	Meperidine	3
	Methadone	4
	Morphine	56
	Oxycodone	177
	Propoxyphene	15
New antinausea/vomiting medications (n=61)	Dolasetron	2
	Ondansetron	59
Old antinausea/vomiting medications (n=204)	Dronabinol	2
	Droperidol	7
	Metoclopramide	110
	Prochlorperazine	38
	Promethazine	42
	Trimethobenzamide	5

Table 1 (Cont'd): Descriptions of Medication Categories

Therapeutic Class (No. of Times Therapeutic Class Medication Administered)	Medications Included in Therapeutic Class and No. of Times Each Medication Administered	
Sedating antihistamines (n=123)	Chlorpheniramine	1
	Cyproheptadine	2
	Diphenhydramine	87
	Hydroxyzine	33
Benzodiazepines (n=261)	Alprazolam	16
	Clonazepam	27
	Diazepam	13
	Chlordiazepoxide	1
	Lorazepam	137
	Midazolam	2
	Oxazepam	2
	Temazepam	58
	Clorazepate	1
	Triazolam	4
Old anticonvulsants (n=55)	Carbamazepine	26
	Divalproex	23
	Valproate sodium	5
	Valproic acid	1
New anticonvulsants (n=215)	Lamotrigine	1
	Levetiracetam	18
	Gabapentin	193
	Topiramate	2
	Oxcarbazepine	1
Anticonvulsants: detrimental to cognition (n=287)	Fosphenytoin	2
	Phenobarbital	9
	Phenytoin	271
	Primidone	5

Abbreviation: SSRIs, selective serotonin reuptake inhibitors.

Statistical Methods

We performed a systematic analysis to examine associations of various neurobehavioral impairments and neurotropic medication categories with stroke rehabilitation outcomes using descriptive statistics, 2-way associations, analysis of variance, correlation analyses, and ordinary least squares or logistic regression analyses. We controlled for important covariates, such as admission functional status (FIM instrument), severity of illness (CSI), and comorbidities, by using detailed patient data contained in the PSROP database.[21]

RESULTS

Descriptive Statistics

Table 1 lists specific medications that were included in each neurotropic medication group. Each group contains multiple medications used in PSROP facilities; however, there is often a predominate medication. For example, gabapentin accounts for 90% of all new anticonvulsants.

Patients with moderate stroke (CMGs 104–107) had different demographic and other characteristics than patients in CMGs 108 to 114 (severe stroke). There were 345 (72.8%) patients in the moderate stroke group who had a documented neurobehavioral impairment or received neurotropic medications, compared with 381 (85.6%) patients in the severe stroke group ($P<.001$) (table 2).

There were several other significant differences between the moderate and severe stroke CMG patient groups. Patients with severe stroke were sicker as measured by admission and maximum CSI scores (higher), more functionally disabled as measured by FIM scores (lower), had higher percentage of hemorrhagic (vs ischemic) strokes, and had longer LOSs. A smaller percentage of patients with severe stroke were discharged to home (73.3% vs 95.2%).

Neurotropic medication use served as a surrogate for indication of neurobehavioral impairment for 23% of patients in both groups.

Associations of Neurologic and Behavioral Impairments With Outcomes by CMGs

Associations between neurobehavioral impairment and outcomes by severity of stroke are shown in table 3. For patients with moderate strokes, having both of the defined components of neurobehavioral impairment (mood and behavior disturbances, cognitive impairment) was associated with the longest LOS (17.3d). Patients with no documentation (diagnosis, chart descriptions, or neurotropic medication use) of neurobehavioral impairment had the shortest LOS (12.9d, $P<.001$) and the highest rate of discharge to home (99.2%).

For patients with severe strokes, having the mood and behavior disturbances component or both components (mood and behavioral disturbances, cognitive impairment) was associated with a longer mean LOS (≥26d), whereas patients in the severe group with no indication of neurobehavioral impairment had the shortest LOS for their group (22.1d, $P=.030$). Also, patients with severe stroke with both components of neurobehavioral impairment had significantly less improvement in motor FIM score and were more likely to be discharged to a skilled nursing facility (SNF). Patients with severe stroke with neurotropic medications only had the largest increase in motor FIM score and the lowest percentage of discharge to an SNF. In addition, the presence of cognitive impairment was associated

Table 2: Descriptive Statistics for Patients in Moderate (CMGs 104–107) and Severe (CMGs 108–114) Stroke Groups

Variables	CMGs 104–107 (n=474)	CMGs 108–114 (n=445)	P
Female (%)	50.0	47.6	.509*
Mean age ± SD	65.4±14.8	67.8±14.1	.013†
Age groups (%)			.224*
19–40y	5.5	3.8	
41–60y	26.4	23.2	
61–80y	52.1	53.0	
>80y	16.0	20.0	
Race (%)			.060*
White	56.5	56.4	
Black	28.1	24.5	
Other	14.4	18.4	
Missing	1.1	0.7	
Side of stroke (%)			.727*
Right	45.4	43.4	
Left	42.8	43.4	
Bilateral	9.1	11.0	
Unknown	2.7	2.3	
Type of stroke (%)			.063*
Hemorrhagic	21.3	26.7	
Ischemic	78.7	73.3	
Neurobehavioral impairments (%)			<.001*
Mood/behavior disturbances	36.5	36.2	
Cognitive impairment	4.4	7.6	
Both	8.9	18.4	
Neurotropic medications	23.0	23.4	
None	27.2	14.4	
Discharge disposition (%)			<.001*
Home/community	95.2	73.3	
SNF	4.8	28.7	
Mean admission CSI continuous score ± SD	16.0±10.2	26.7±14.7	<.001†
Mean maximum CSI continuous score ± SD	23.3±14.2	40.1±21.9	<.001†
Mean discharge CSI continuous score ± SD	6.0±6.8	14.1±12.9	<.001†
Mean increase (maximum − admission) in CSI score ± SD	7.3±8.0	13.4±12.2	<.001†
Mean admission motor FIM score ± SD	47.9±5.6	27.0±7.1	<.001†
Mean discharge motor FIM score ± SD	70.2±9.4	51.5±16.3	<.001†
Mean Increase motor FIM score ± SD	22.4±8.8	24.5±13.9	.006†
Mean admission cognitive FIM score ± SD	24.2±7.2	16.9±7.7	<.001†
Mean discharge cognitive FIM score ± SD	27.9±6.0	22.2±7.6	<.001†
Mean increase cognitive FIM score ± SD	3.7±3.7	5.3±4.6	<.001†
Mean LOS ± SD	15.2±7.2	24.9±10.5	<.001†

Abbreviations: SNF, skilled nursing facility; SD, standard deviation.
*Chi-square test.
†*t* test.

most strongly with a higher percentage of patients discharged to an SNF in both the moderate and severe stroke groups.

Table 4 presents significant associations between neurotropic medication groups and 2 outcomes: rehabilitation LOS and increases in motor FIM score. Patients with moderate and severe stroke who received medications within specific neurotropic medication groups are compared with all patients in each group, controlling for patient characteristics (listed below table 4). Patients with moderate stroke (n=20) who were given atypical antipsychotic medications are compared with a control group of patients with moderate stroke who did not receive any atypical antipsychotic medicine. Patients given atypical antipsychotics statistically had the same LOS (15.7d) but a significantly improved motor FIM score with a change of 27.8 points as compared with the overall mean LOS and change in motor FIM score for the moderate stroke control group (15.2d and 22.4 points, respectively).

For patients with moderate stroke, neurotropic medication groups associated with significantly longer rehabilitation LOSs were the traditional antipsychotics, modafinil, hypnotics, anxiolytics, anti-Parkinson's medications, and newer selective serotonin reuptake inhibitors (SSRIs). Newer SSRIs, atypical antipsychotics, and opioid analgesics were associated with significantly greater increase in motor FIM score. Use of older antinausea medications, tricyclic antidepressants, anti-Parkinson's medications, muscle relaxants, neurostimulants, and older SSRIs was associated with significantly less increase in motor FIM score.

For patients with severe strokes, use of muscle relaxants, anti-Parkinson's medications, anxiolytics, hypnotics, new antinausea medications, sedating antihistamines, or traditional antipsychotics was associated with significantly longer rehabilitation LOSs. For these same severe patients, use of older SSRIs, anti-Parkinson's medications, and modafinil was associated with significantly less improvement in motor FIM score,

Table 3: Bivariate Associations of Neurobehavioral Impairment With Outcomes by CMG Group

Variables	Mood/Behavior Disturbances (n=334)	Cognitive Impairment (n=55)	Both Mood/Behavior Disturbances and Cognitive Impairment (n=124)	Neurotropic Medications (No Mood/Behavioral/Cognitive Impairment Signs Recorded) (n=213)	None (n=193)	P
LOS (d)						
CMGs 104–107 (n)	173	21	42	109	129	
Mean LOS ± SD	16.2±6.5	15.2±6.8	17.3±9.1	15.4±7.9	12.9±6.3	<.001*
CMGS 108–114 (n)	161	34	82	104	64	
Mean LOS ± SD	26.4±9.9	22.6±9.4	26.0±12.3	24.2±10.7	22.1±9.4	.030*
Mean increase motor FIM score ± SD						
CMGs 104–107	22.5±8.5	22.1±10.2	20.5±7.1	21.5±10.1	23.5±8.1	.271*
CMGs 108–114	25.4±13.2	21.8±22.4	20.6±14.3	26.4±11.5	25.4±12.6	.034*
Discharge disposition (%)						
CMGs 104–107						<.001†
Home	97.1	81.0	85.7	93.6	99.2	
SNF	2.9	19.0	14.3	6.4	0.8	
CMGs 108–114						.003†
Home	72.7	61.8	61.0	83.7	79.7	
SNF	27.3	38.2	39.0	16.3	20.3	

NOTE. CMGs 104–107: moderate stroke; CMGs 108–114: severe stroke.
*Analysis of variance.
†Chi-square test.

but use of hypnotics was associated with significantly more improvement in motor FIM.

Tables 5 and 6 show, for each PSROP facility, the percentage of patients who received medications in the neurotropic medication groups found to be associated with better or poorer outcomes (see table 4). Use of neurotropic medications varied significantly among the facilities for patients with moderate (see table 5) and severe strokes (see table 6), with the latter group having the greatest variation. Site variation is noticeable in the increase or decrease of neurotropic medication use as the severity of the stroke increases. For example, at site 4, use of new SSRIs is infrequent for all patients and use of old SSRIs increases from 27% for patients with moderate stroke (see table 5) to 52% for patients with severe stroke (see table 6). In contrast, at site 5

Table 4: Associations of Types of Medications and Outcomes by CMG Groups

Variables	CMG 104–107 (n=474)			CMG 108–114 (n=445)		
Therapeutic Medication Class	n	Mean LOS (mean, 15.2)*	Mean Increase Motor FIM Score (mean, 22.4)*	n	Mean LOS (mean, 24.9)†	Mean Increase Motor FIM Score (mean, 24.5)†
Atypical antipsychotics	20	15.7 (+0.5)	27.8‡ (+5.4)	53	26.9 (+2.0)	25.6 (+1.1)
Traditional antipsychotics	7	18.4§ (+3.2)	22.1 (−0.3)	10	37.4‡ (+12.5)	24.5 (same)
Tricyclic antidepressants	15	18.6 (+3.4)	20.2§ (−2.2)	21	25.1 (+0.2)	25.8 (+1.3)
Old SSRIs	90	16.5 (+1.3)	21.3§ (−1.1)	104	25.8 (+0.9)	21.4‖ (−3.1)
New SSRIs	31	19.5§ (+4.3)	24.2§ (+1.8)	59	29.3 (+4.4)	25.9 (+1.4)
Analgesic; muscle relaxant	23	18.0 (+2.8)	19.3‡ (−3.1)	43	30.2‡ (+5.3)	23.0 (−1.5)
Anti-Parkinson's medications	41	18.0§ (+2.8)	18.1‖ (−4.3)	68	28.4‡ (+3.5)	22.8‡ (−1.7)
Anxiolytics	4	23.8§ (+8.6)	19.8 (−2.6)	13	36.2‡ (+11.3)	27.6 (+3.1)
Hypnotics	87	17.2§ (+2.0)	21.5 (−0.9)	96	28.1‡ (+3.2)	27.5‡ (+3.0)
Modafinil	2	32.0 (+16.8)	29.0 (+6.6)	32	27.7 (+2.8)	21.1§ (−3.4)
Neurostimulants	16	19.9 (+4.7)	18.0‖ (−4.4)	57	28.4 (+3.5)	22.1 (−2.4)
Opioid analgesics	86	15.8 (+0.6)	24.7‡ (+2.3)	115	27.1 (+2.2)	25.2 (+0.7)
New antinausea/vomiting medications	15	15.9 (+0.7)	21.3 (−1.1)	34	29.2§ (+4.3)	24.7 (+0.2)
Old antinausea/vomiting medications	41	17.3 (+2.1)	20.0‡ (−2.4)	76	27.3 (+2.4)	24.7 (+0.2)
Sedating antihistamines	43	16.8 (+1.6)	23.5 (+1.1)	31	29.8§ (+4.9)	26.6 (+2.1)

NOTE. Values are means for patients with the specified medication and, in parentheses, the difference between cell mean value and overall mean for all patients in the CMG. Patient characteristics controlled in regression analyses include sex, age, race, side of stroke, type of stroke, mental status, pre–prospective payment system, discharge disposition, maximum CSI continuous score, admission motor FIM score, and admission cognitive FIM score.
*Mean of entire group (n=474).
†Mean of entire group (n=445).
‡Significance of variable between .001 and .01 in multiple regression analyses of outcome, controlling for patient characteristics.
§Significance of variable between .01 and .05 in multiple regression analyses of outcome, controlling for patient characteristics.
‖Significance of variable less than .001 in multiple regression analyses of outcome, controlling for patient characteristics.

Table 5: Percentage of Patients With Moderate Stroke (CMG 104–107) Using Specified Medication Categories by Site

Therapeutic Medication Class	Sites						P*
	1	2	3	4	5	6	
Atypical antipsychotics	4.1	4.4	4.3	1.8	11.9	2.2	.049
Tricyclic antidepressants	4.1	2.2	4.3	5.4	1.7	1.1	.529
Old SSRIs	13.7	14.3	12.8	26.8	17.0	22.8	.098
New SSRIs	2.7	11.0	2.1	4.5	18.6	2.2	<.001
Analgesic; muscle relaxant	0.0	2.2	4.3	11.6	5.1	3.3	.005
Anti-Parkinson's medications	1.4	23.1	0.0	0.0	5.1	17.4	<.001
Hypnotics	37.0	34.1	10.6	8.0	25.4	0.0	<.001
Neurostimulants	2.7	3.3	4.3	0.0	10.2	3.3	.029
Opioid analgesics	4.1	23.1	36.2	14.3	25.4	15.2	<.001
New antinausea/vomiting medications	1.4	2.2	6.4	1.8	11.9	0.0	<.001
Old antinausea/vomiting medications	2.7	18.7	12.8	7.1	11.9	1.1	<.001

*Chi-square test.

the overall use of old SSRIs is less frequent and the use of newer SSRIs increases as stroke severity increases.

DISCUSSION

Patients with severe strokes (CMGs 108–114) were older; were sicker at admission to, discharge from, and during their rehabilitation stays (CSI scores); were less likely to be discharged to home; and had longer LOSs than patients with moderate strokes. However, both patients with severe and moderate strokes had about the same increase in motor FIM and cognitive FIM scores from admission to discharge from rehabilitation. Within the moderate and severe stroke CMG groupings patients with no neurobehavioral impairments (no mood or behavior disturbances, no cognitive impairment, and no use of neurotropic medications) had the shortest LOSs and larger increases in motor FIM. When severity of illness (CSI) and its related components were not allowed to enter models by not including them in the variable selection list, the R^2 and c statistics changed little. Because none or very few of the other predictors changed, the models were stable.

We found several neurotropic medications associated with better outcomes and others that were associated with poorer outcomes. These varied by patient characteristics and severity of stroke. Generally, the newer medications (eg, newer SSRIs, atypical antipsychotics) were associated with better outcomes. Newer SSRIs were associated with greater improvement in FIM scores but also were associated with longer LOSs, making it difficult to draw definite conclusions about overall benefit. Older antinausea medications were associated with less FIM improvement for patients with moderate stroke and had no effect on LOS, suggesting a rationale for using the newer antinausea agents in this patient population, because the older antinausea medications may reduce FIM efficiency. Finally, atypical antipsychotics generally were associated with more increase in motor FIM score (primarily in the moderate stroke group), corresponding to our initial hypothesis that the more favorable side-effect profile of the atypical antipsychotic medication group in patients with stroke should translate into better outcomes.

Most facilities used newer medications sparingly. However, site 5 used newer SSRIs, newer antinausea medications, neurostimulants, and atypical antipsychotic medications more frequently, for patients with both moderate and severe stroke. After controlling for many patient characteristics (see table 2), we found that the association of neurobehavioral impairments with better or poorer outcomes in bivariate analyses remained significant in multiple regression analyses for LOS and increase in motor FIM score. That is, after using more thorough efforts to control for multiple patient characteristics in multiple

Table 6: Percentage of Patients With Severe Stroke (CMG 108–114) Using Specified Medication Categories by Site

Therapeutic Medication Class	Sites						P*
	1	2	3	4	5	6	
Atypical antipsychotics	4.9	7.6	3.4	2.2	40.7	4.9	<.001
Traditional antipsychotics	3.7	4.6	1.7	0.0	1.1	2.4	.533
Tricyclic antidepressants	3.7	1.5	10.1	4.4	1.1	4.9	.035
Old SSRIs	24.4	15.2	18.5	52.2	12.1	41.5	<.001
New SSRIs	2.4	13.6	5.9	8.7	37.4	7.3	<.001
Other antidepressants	8.5	21.2	58.8	15.2	49.5	48.8	<.001
Analgesic; muscle relaxant	3.7	9.1	10.1	15.2	12.1	9.8	.339
Anti-Parkinson's medications	1.2	48.5	10.1	0.0	3.3	48.8	<.001
Anxiolytics	4.9	0.0	4.2	4.4	1.1	2.4	.391
Hypnotics	32.9	60.6	4.2	6.5	23.1	0.0	<.001
Modafinil	0.0	0.0	0.0	0.0	35.2	0.0	<.001
Neurostimulants	11.0	7.6	5.9	2.2	30.8	17.1	<.001
Opioid analgesics	4.9	24.2	42.0	23.9	36.3	2.4	<.001
New antinausea/vomiting medications	2.4	0.0	4.2	2.2	27.5	2.4	<.001
Old antinausea/vomiting medications	15.9	30.3	18.5	6.5	14.3	12.2	.021

*Chi-square test.

sequences and combinations, outcomes consistently were better for patients with atypical antipsychotic medications than without.

There are a number of questions that can he raised about these initial observations. Many of these medications may have been used off-label in ways that their medication category description would not suggest. For instance, low-dose chlorpromazine is often used as a cure for intractable hiccups, and haloperidol is rarely used in poststroke rehabilitation except in the case of an elderly person who may be demented and experiencing sundowning. Use of anti-Parkinson's neurostimulants has entirely different implications in the absence of Parkinson's disease (of all the study patients who were given anti-Parkinson's medications, only 3.9% had a documented diagnosis of Parkinson's disease). Future analyses will attempt to understand discrepant uses of medications of interest.

However, there is evidence in the literature that these medications might be beneficial and justifies investigation of their effectiveness. During the early 1980s, studies were conducted on animals investigating the use of adrenergic agents on brain recovery after injury.[30-32] Later, Gualtieri[33] and Goldstein[17] published articles advocating that other adrenergic agents, as well as their precursors, could facilitate recovery. Studies on the use of dopamine agonists (so-called "anti-Parkinson agents") for brain injury in humans began in the 1990s, showing that these agents also could be used to help initiation and attention in these patients.[34-40] Dopamine agonists have since been used commonly in the treatment of brain injury. The use of dopamine agonists in patients with stroke so far has been limited to anecdotal or pilot studies; however, these articles are suggestive of their ability to facilitate cognitive capacity and recovery.

A meta-analysis of 7 generally high-level studies involving a total of 172 patients suggested that amphetamine treatment reduced death and dependence and relatively improved motor and language function.[41] However, there were too few patients to draw any definite conclusions about effects of amphetamine treatment on recovery from stroke. A randomized, double-blind, placebo-controlled trial of 40 subjects using intravenous amantadine or placebo for 5 days showed statistically significant improvements in cadence, length of heel-to-toe movements in the single support phase, and variability in double support phase and double support time.[42] A prospective, randomized, placebo-controlled, double-blind study of physical therapy combined with 3 weeks of daily levodopa or placebo and then 3 weeks of physical therapy alone showed increased motor function at both endpoints. Finally, 21 stroke survivors randomized to methylphenidate or placebo for 3 weeks scored lower on one depression scale and higher on a functional scale.[43]

Atypical antipsychotics, particularly olanzapine, have been reported to enhance cognitive function, providing a possible basis for the positive association of these medications with better outcomes during stroke rehabilitation.[44-46] These positive reports need to be balanced with recent controversy about the off-label use of atypical antipsychotics in the management of elderly patients with dementia. A U.S. Food and Drug Administration Public Health Advisory[47] in April 2005 warned that a review of 17 controlled trials involving the use of atypical antipsychotics in elderly demented patients showed a 1.6- to 1.7-fold increase in mortality, mostly because of heart-related events and pneumonia. Like the present study, this report only indicates an association of increased mortality with these medications in a population with some similarity to our stroke population, not a cause-and-effect relation. Caution and further investigation are needed to confirm these findings.

Finally, we have not yet examined the specific ramifications of medication dosing, duration, or timing or medications being given simultaneously or in sequence. Nonetheless, these findings add to the body of quantified knowledge of how a stroke survivor is treated during poststroke inpatient rehabilitation and strengthen previously established observations that limiting access to newer medications may lead to higher overall costs through longer LOSs without concomitant improvements in motor FIM score change or rate of discharge to community.[18,48]

CONCLUSIONS

We found significant differences in the ways stroke rehabilitation physicians approach common neurocognitive impairments after stroke and in the choice of medications to lessen their negative impacts. This exploration of neurotropic medication utilization practice patterns and outcomes can be used to guide the design of future studies to enhance the efficient use of inpatient stroke rehabilitation resources and improve patient outcomes. Although they do not confirm a cause-and-effect relation, our results indicate that certain medications or classes of medications are associated with positive and negative effects on stroke rehabilitation outcomes and should be studied further.

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ORIGINAL ARTICLE

Nutrition Support (Tube Feeding) as a Rehabilitation Intervention

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ABSTRACT. James R, Gines D, Menlove A, Horn SD, Gassaway J, Smout RJ. Nutrition support (tube feeding) as a rehabilitation intervention. Arch Phys Med Rehabil 2005; 86(12 Suppl 2):S82-92.

Objective: To describe site variation in use of enteral feeding and its association with stroke rehabilitation outcomes, controlling for a variety of confounding variables.

Design: Prospective observatioual cohort study.

Setting: Six inpatient rehabilitation facilities in the United States.

Participants: Patients (N=919) from the Post-Stroke Rehabilitation Outcomes Project database with moderate or severe stroke who were discharged to home, community, or skilled nursing facility.

Interventions: Not applicable.

Main Outcome Measures: Change in total, motor, and cognitive FIM instrument scores and change in severity of illness.

Results: Monitoring of nutritional status and the frequency of tube-feeding interventions for patients with moderate and severe stroke varied significantly among sites. Patients with tube feeding had higher severity of illness and lower functioning on admission compared with patients who did not receive tube feeding. However, when we controlled for severity of illness, admission FIM score, and other important covariates, we found that patients witb severe strokes who were tube fed for more than 25% of their stay bad greater increases in total, motor, and cognitive FIM scores and greater improvement in severity of illness by discharge.

Conclusions: Nutrition support (tube feeding) is an effective therapy in rehabilitation service for patients with severe strokes and is associated with greater motor and cognitive improvements, even in patients with the most severe strokes.

Key Words: Cerebrovascular accident; Nutrition; Outcome assessment (health care); Rehabilitation; Severity of illness index; Tube feeding.

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MANY PATIENTS IN STROKE rehabilitation have some degree of malnutrition, either from prior poor food intake or from demands imposed by the stroke and hospitalization.[1] It is a known problem in stroke patients, with a prevalence of 16% on admission that increases to 22% to 35% at about 2 weeks and up to 50% at 2 to 3 weeks.[2-4] Malnourished people may lack the energy, stamina, strength, and mental focus to participate fully in therapies.[5,6] The effect of poor nutritional status on patients with stroke has been associated with poorer outcomes, such as reduced functional improvement, longer lengths of stay (LOSs), increased rates of complications, and mortality.[7,8] However, nutrition is often overlooked or not included as an important poststroke rehabilitation intervention, although it has been shown to be a foundation for effective therapy.[9]

Most inpatient rehabilitation facility patients have varying degrees of limitations related to eating, such as dysphagia, cognitive impairment, limited mobility, and movement.[10] Often enteral (using the gastrointestinal system) feeding by mouth, although the most natural and desirable feeding method, is complicated by a lack of ability to self-feed, chewing or swallowing difficulties, poor appetite, and prior food preferences and patterns that are closely linked to malnutrition, weight loss, and decreased strength.[11] Altered-consistency diets (eg, puree, blended, or ground foods) and thickened liquids frequently are given to patients with chewing and swallowing difficulties but may be unappealing and contribute to poor intake. Nutritional support (enteral feeding by tube) provides adequate nutrition and is not affected by reduced appetite, swallowing problems, limited self-feeding, or disease conditions in which the gastrointestinal system is compromised. Tube feeding enhances continued physical recovery, supports earlier initiation of rehabilitation efforts, and may reduce aspiration related to dysphagia.[12]

Optimal timing to initiate tube feeding and for which patients have not been defined clearly.[13,14] The decision begins, in most cases, during the acute hospital stay before rehabilitation. A physician assesses each patient and if the patient is deemed to be at risk for aspiration based on diagnosis or poor tolerance of oral intake, a referral is made for a bedside (or clinical) swallow study. Approximately 60% of aspiration occurs without sensation or outward signs and symptoms and often would not be diagnosed from clinical examination.[15] Therefore, if a patient appears at risk for silent aspiration or if further assessment is warranted, an instrumental swallow study is performed. If a safe diet can be established during a clinical or instrumental examination, with or without the use of compensatory strategies and diet modification, all attempts are made to maintain an oral route. If a patient is unable to meet nutritional needs and/or adequately protect his/her airway witb oral intake, then temporary alternative measures for nutrition and hydration, such as tube feeding, are recommended.[16-18] However, the time between trying to feed by oral intake and identifying that oral intake is unable to meet a patient's nutri-

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tional needs delays the initiation of tube feeding, which may result in nutritional decline.[19]

Clinicians must weigh the perceived risk of silent aspiration caused by dysphagia against the known association of nasogastric tubes that are used commonly for short-term tube feedings with increased rates of aspiration pneumonia.[20-24] To truly weigh the risks, it is important to understand the full benefit of tube feeding on functional status and cognition.

The aim of this article was to describe the variation of nutritional support interventions, specifically tube feeding, used during poststroke inpatient rehabilitation and to determine the association of tube-feeding interventions with functional and clinical outcomes and patients' abilities to participate in physical therapy (PT), occupational therapy (OT), and speech and language pathology (SLP) sessions. Our hypothesis was that patients who present with similar functional and cognitive levels (measured by FIM instrument scores) and severity of illness (measured by the Comprehensive Severity Index [CSI]) and who receive tube feeding during acute rehabilitation to provide additional nutritional support have better participation in therapies and, hence, better outcomes. This may be the first study to explore site variation in tube-feeding practice in inpatient rehabilitation and associate tube-feeding interventions with rehabilitation outcomes.[24]

METHODS

Patient Sample

We used the Post-Stroke Rehabilitation Outcomes Project (PSROP) database[25] to explore tube feeding as a stroke intervention and its association with amount of therapy time and rehabilitation outcomes for patients with moderate or severe strokes. The PSROP database contains patient characteristics and process and outcome data for 1161 consecutively enrolled adult (>18y) stroke patients in 6 inpatient rehabilitation facilities across the United States. Stroke was defined as having an *International Classification of Diseases, 9th Revision* (ICD-9),[26] code of 430 to 438.99, 997.02, or 852 to 853 for the rehabilitation admission. Mild, moderate, and severe strokes were classified by case-mix groups (CMGs) of 100 to 103, 104 to 107, and 108 to 114, respectively. Patients with mild stroke were not included in the sample because of the low frequency of tube feeding (2.9%). In addition, patients with missing CMGs were not included. The PSROP sample was reduced from a total of 1161 to 919 patients, with 474 moderate strokes and 445 severe stroke patients who were discharged to home, the community, or a skilled nursing facility.[25]

Functional status was determined using total and component (motor, cognitive) FIM scores on admission and discharge. Severity of illness was measured for 3 time periods: admission (first 24h of rehabilitation), discharge (last 24h of rehabilitation), and maximum (entire rehabilitation stay including admission and discharge), as measured by the CSI based on signs and symptoms extracted from the medical record.

Tube-feeding data were abstracted from inpatient rehabilitation charts after patient discharge. Data abstractors entered the date of, type of, and reason for tube placement. Start and stop times of an enteral formula, amount, and delivery frequency were collected from physician orders. Based on those data, the 919-patient sample of moderate and severe stroke patients was divided into 4 tube-feeding groups: (1) no tube feeding (n=758); (2) tube feeding for less than 25% of the rehabilitation stay (n=17) with tube feeding discontinued before discharge; (3) tube feeding for 25% or more of the rehabilitation stay with tube feeding discontinued before discharge (n=109); and (4) tube feeding for 100% of stay and discharged on tube-feeding support (n=35). The last group was defined by the following criteria: (1) a patient's last ordered diet type was nothing by mouth or a speech and language pathologist was supervising all oral intake, (2) the patient was unable to swallow liquids or solids 24 hours before discharge, (3) a percutaneous endoscopic gastrostomy or other gastrostomy tube had been placed, and (4) the patient was discharged to a skilled nursing facility or home health agency. Group 4 patients never advanced to sufficient oral intake.

Patient Variables

Patient variables include sex; age; race; payer source; previous stroke; hypertension diagnosis; diabetes diagnosis; depression diagnosis; any other mental disorder diagnosis; body mass index (BMI) on admission (categorized as underweight [$<18.5 kg/m^2$], normal [$18.5–24.9 kg/m^2$], overweight [$25.0–29.0 kg/m^2$], obese [$\geq 30.0 kg/m^2$]); type, location, and side of stroke; number of days from onset of stroke symptoms to admission to rehabilitation; admission motor and cognitive FIM scores; admission CSI continuous scores; and nutritional risk. Higher FIM scores indicate higher functioning levels, and higher CSI scores indicate increased severity of illness, or sicker patients. Nutritional risk was defined by using the first serum albumin or prealbumin level measurement. A patient was considered to be at high nutritional risk if the first serum albumin level was less than 2.5g/dL or if the first prealbumin level was less than 15mg/dL, moderate risk if the first albumin level was 2.5 to 3.0g/dL or the first prealbumin level was 15 to 20g/dL, low risk if the first albumin level was 3.0 to 3.5g/dL or the first prealbumin level was 20 to 25mg/dL, or no risk if the first albumin level was greater than 3.5g/dL or the prealbumin level was greater than 25mg/dL.

Process Variables and Interventions

Process variables include inpatient rehabilitation LOS, tube feeding, and average number of therapy minutes per patient per day for PT, OT, and SLP sessions calculated by dividing the number of total minutes in each type of therapy by the LOS.

Outcome Variables

Primary outcome measures include improvements in functioning using the difference between admission and discharge total, motor, and cognitive FIM scores. Secondary outcome measures include improvements in severity of illness (CSI) from admission to discharge (net medical improvement), increase in severity of illness (CSI) from admission to maximum, change in weight from the first to last weight measurments, mental disorder diagnosis (ICD-9 codes starting with 781, 294, 305, 309, 310, 311), depression diagnosis (ICD-9 codes 311−311.99), pneumonia diagnosis (ICD-9 codes starting with 480−486, 507), and improvement in nutritional status, defined as a decrease in nutritional risk from the first to last measured albumin and/or prealbumin level. Larger differences in FIM score and net medical improvement (CSI) scores signify more recuperation. Larger increases in CSI from admission to maximum signify a worsening condition at some time during the rehabilitation stay. Discharge destination was not used as an outcome variable in regression analysis because it was used to define the group of patients discharged with tube feeding.

Statistical Methods

Descriptive statistics were used to compare patient characteristics, therapy interventions, and outcomes for the 4 tube-feeding groups, along with site variation in tube feeding and common nutrition assessment measures. Chi-square tests were

used for categoric data, and analysis of variance was used for continuous data.

Ordinary least squares (OLS) regression was used to identify associations between patient characteristics and the tube-feeding groups with continuous outcome variables. To avoid multicollinearity, only variables with a correlation coefficient less than .50 were allowed to enter regression models for patients with moderate and severe stroke. Stepwise selection was used at a significance level of .10 to allow independent variables to enter and leave each model. The final models were the most parsimonious, with the maximum number of variables with significance levels less than .05. All analyses were performed with SAS statistical software, release 8.2.[a]

RESULTS

To understand the associations of tube feeding with outcomes, we begin by assessing similarities and differences in patients with moderate (CMG 104–107) and severe (CMG 108–114) strokes who received tube feeding compared with those who did not.

Patient Variables

Patient characteristics by tube-feeding group are presented in table 1. Almost 6% of patients with moderate strokes and 30% of patients with severe strokes received tube feeding during rehabilitation.

Demographic and health plan characteristics. There were no significant differences in demographic characteristics for sex or age by tube-feeding groups for moderate or severe stroke patients. Racial differences were significant in the severe stroke group. Most patients discharged on tube-feeding support had Medicare insurance (60.0% and 73.3% for moderate and severe strokes, respectively).

Health and functional status characteristics. Nutritional risk, as defined by albumin/prealbumin level, varied significantly by tube-feeding group for patients with moderate and severe stroke ($P<.001$). Thirty-three percent of patients with moderate stroke and 38% of patients with severe stroke who received any tube feeding were at moderate or high nutritional risk. For patients at high nutritional risk, 73% with moderate strokes and 60% with severe strokes received no tube feeding during rehabilitation. Many patients who received tube feeding (44% with moderate stroke, 26% with severe stroke) had no albumin or prealbumin measurements taken during rehabilitation.

In the moderate stroke group, more patients who received tube feeding were overweight or obese (70.4%) compared with those without tube feeding (53.5%, $P<.001$). For the severe stroke group there were proportionately more overweight and obese patients in the non–tube-feeding group (59.8%) than in the tube-feeding group (54.5%) ($P=.035$).

Stroke risk factors and stroke type and side were not significantly different among tube-feeding groups. Most tube-fed patients with moderate strokes had brainstem/subcortical and lobar strokes ($P=.006$).

FIM and CSI. Patients who received tube feeding differed significantly in function and severity of illness from patients who did not receive tube feeding. Tube-fed patients with moderate and severe stroke had significantly lower admission total and cognitive FIM scores and higher CSI admission scores. In addition, patients with severe stroke also had lower admission motor FIM scores.

When examining criteria used to determine CSI severity of illness for the tube-feeding groups, we found that the most severe symptoms of dysphagia (unable to swallow solids or liquids) were associated with tube-feeding groups. That is, almost all patients who were tube fed were unable to swallow solids or liquids or had dysphagia "not otherwise specified." However, there were 31 patients with moderate stroke and 38 patients with severe stroke who were unable to swallow solids or liquids and were not tube fed (see table 1, Maximum CSI Indicator Dysphagia).

Process Variables

Process variables by tube-feeding group are presented in table 2.

Length of stay. Rehabilitation LOSs in tube-feeding groups differed for patients with moderate and severe stroke. For patients with moderate stroke, the mean LOS for patients who were discharged with tube-feeding support (16.8d) was closer to the mean of patients not tube fed (15.0d), both of which were less than that for patients who were tube fed for 1% to 24% and 25% or more of their stay (20d and 8.7d, respectively; $P=.079$). For patients with severe stroke, again the mean LOS for patients who were discharged with tube-feeding support (23.1) was closer to the mean LOS for patients not tube fed (23.6d), both of which were shorter than for patients who were tube fed for 1% to 24% and 25% or more of their stay (34.2, 28.7d, respectively; $P<.001$).

Therapy. For the moderate stroke group, tube feeding was not associated with the average number of days, total minutes, or minutes per patient per day spent in PT or OT sessions. However, for the severe stroke group, patients with tube feeding spent significantly fewer minutes per day in PT and OT compared with patients with no tube feeding ($P<.025$). For both stroke severity levels, SLP minutes per day were higher for patients receiving tube feeding, although the difference was significant for patients with moderate strokes only.

Outcome Variables

Outcome variables by tube-feeding group are presented in table 3.

Nutritional status. Significant differences in improvements in nutritional status (change in albumin or prealbumin levels from admission to discharge) for patients who did or did not receive tube feeding were found in the severe stroke group ($P=.022$). Patients with tube feeding showed more improvement.

Depression. We found that significantly more patients with moderate and severe stroke who were tube fed had a depression diagnosis, compared with patients without tube feeding ($P=.037$ vs $P=.047$, respectively).

Discharge FIM and CSI scores. At discharge, patients receiving tube feeding for 1% to 24% and 25% or more of their stay had similar discharge motor, cognitive, and total FIM scores as the non–tube-feeding group. However, these scores differed significantly from those of patients who were discharged on tube feeding ($P<.001$). Larger increases in FIM (total, motor, cognitive) scores were seen in the 2 tube-fed patient groups (tube fed for 1%–24% and ≥25% of stay); increases were significantly less for patients discharged on tube feeding. At discharge, patients receiving tube feeding for 1% to 24% and 25% or more of their stay had similar discharge CSI scores as the non–tube-feeding group. However, these scores were significantly lower than scores for patients who were discharged on tube feeding ($P<.001$).

Site Variation

We examined variation in tube-feeding interventions and nutritional assessment measures across the 6 facilities (table 4).

For patients with moderate stroke, the percentage of patients with tube feeding for 1% to 24% of stay varied little by site

Table 1: Patient Variables for Moderate and Severe Strokes by Tube-Feeding Group

Variables	Moderate Stroke (CMGs 104–107)					Severe Stroke (CMGs 108–114)				
	No Tube Feeding (n=447)	Tube Feeding 1%–24% of Stay (n=4)	Tube Feeding ≥25% of Stay (n=18)	Tube Feeding 100% of Stay; Discharged with Tube Feeding (n=5)	Variation Significance (*P*)	No Tube Feeding (n=311)	Tube Feeding 1%–24% of Stay (n=13)	Tube Feeding ≥25% of Stay (n=91)	Tube Feeding 100% of Stay; Discharged with Tube Feeding (n=30)	Variation Significance (*P*)
Demographics										
Male (%)	49.7	50.0	55.6	60.0	.931*	51.1	61.5	55.0	53.3	.829*
Age (y)	65.3±14.9	60.7±5.3	66.4±14.7	68.8±14.5	.861†	68.1±13.9	64.3±15.1	66.4±14.5	70.2±14.5	.428†
Race (%)					.342*					.023*
White	55.9	75.0	61.1	80.0		51.5	61.5	67.0	73.3	
Black	29.1	25.0	11.1	0.0		28.6	30.8	14.3	10.0	
Other	15.0	0.0	27.8	20.0		19.9	7.7	18.7	16.7	
Payer (%)					.015*					.008*
Medicare	54.6	25.0	66.7	60.0		64.6	23.1	56.0	73.3	
Medicaid	11.6	0.0	5.6	0.0		10.6	0.0	12.1	16.7	
Commercial	32.0	75.0	22.2	20.0		21.2	61.5	26.4	6.7	
Self-pay	1.3	0.0	0.0	20.0		2.6	15.4	4.4	3.3	
Unknown/missing	0.5	0.0	5.6	0.0		1.0	0.0	1.1	0.0	
Health and functional status characteristics										
Nutritional risk by first albumin/prealbumin level (%)					<.001*					<.001*
No nutritional risk	11.0	0.0	5.6	20.0		10.9	7.7	4.4	3.3	
Low nutritional risk	13.4	0.0	22.2	0.0		18.0	23.1	38.5	13.3	
Moderate nutritional risk	7.8	25.0	11.1	0.0		9.6	30.8	18.7	23.3	
High nutritional risk	3.6	0.0	22.2	40.0		10.9	7.7	17.6	20.0	
No albumin/prealbumin measurement	64.2	75.0	38.9	40.0		50.5	30.8	20.9	40.0	
BMI (%)					<.001*					.035*
Underweight (<18.5kg/m^2)	2.9	0.0	11.1	40.0		1.6	7.7	8.8	6.7	
Normal (18.5–24.9kg/m^2)	43.6	25.0	16.7	0.0		38.6	38.5	34.1	46.7	
Overweight (25–29kg/m^2)	32.9	25.0	61.1	60.0		36.3	38.5	40.7	40.0	
Obese (≥30kg/m^2)	20.8	50.0	11.1	0.0		23.5	15.4	16.5	6.7	
Stroke risk factors (%)										
Previous stroke (exclude TIA)	27.5	0.0	44.4	40.0	.224*	33.4	30.8	20.9	26.7	.141*
Hypertension diagnosis	77.4	75.0	72.2	80.0	.961*	83.6	76.9	81.3	76.7	.721*
Diabetes diagnosis	27.1	0.0	27.8	40.0	.590*	33.8	15.4	35.2	33.3	.564*
Type of stroke (%)					.314*					.042*
Hemorrhagic	21.5	50.0	16.7	0.0		24.4	46.2	35.2	16.7	
Ischemic	78.5	50.0	83.3	100.0		75.6	53.8	64.8	83.3	

Table 1: (Cont'd) Patient Variables for Moderate and Severe Strokes by Tube-Feeding Group

Variables	Moderate Stroke (CMGs 104–107)					Severe Stroke (CMGs 108–114)				
	No Tube Feeding (n=447)	Tube Feeding 1%–24% of Stay (n=4)	Tube Feeding ≥25% of Stay (n=18)	Tube Feeding 100% of Stay; Discharged with Tube Feeding (n=5)	Variation Significance (*P*)	No Tube Feeding (n=311)	Tube Feeding 1%–24% of Stay (n=13)	Tube Feeding ≥25% of Stay (n=91)	Tube Feeding 100% of Stay; Discharged with Tube Feeding (n=30)	Variation Significance (*P*)
Side of stroke (%)					.193*					.557*
Right	46.1	25.0	33.3	40.0		44.7	38.5	42.9	33.3	
Left	42.5	75.0	44.4	40.0		43.7	53.9	38.5	50.0	
Bilateral	8.7	0.0	22.2	0.0		9.0	7.7	16.5	16.7	
Unknown	2.7	0.0	0.0	20.0		2.6	0.0	2.2	0.0	
Location of stroke (%)					.006*					.447*
Brainstem/cerebellum	22.6	25.0	22.2	0.0		15.4	0.0	11.0	13.3	
Subcortical	34.0	0.0	27.8	20.0		43.7	53.9	36.3	33.3	
Brainstem + subcortical	4.5	50.0	16.7	0.0		3.2	7.7	5.5	0.0	
Lobar	33.8	25.0	33.3	60.0		32.5	38.5	41.8	50.0	
Unknown	5.2	0.0	0.0	20.0		5.1	0.0	5.5	3.3	
Days onset to rehabilitation admission	10.6±11.5	35.3±30.9	13.2±17.0	5.6±1.5	.002†	15.8±28.7	12.8±8.0	21.9±29.5	23.6±35.9	.186†
FIM										
Admission total FIM score	72.5±9.8	61.5±9.0	67.4±10.4	64.2±16.2	.006†	47.7±11.7	32.9±9.1	35.8±10.7	33.2±11.3	<.001†
Admission motor FIM score	48.0±5.6	42.5±1.0	47.9±5.8	46.2±7.2	.238†	29.0±6.4	21.3±5.3	22.6±6.6	22.3±7.7	<.001†
Admission cognitive FIM score	24.5±7.1	19.0±8.5	19.4±7.1	18.0±9.4	.002†	18.7±7.5	11.6±4.5	13.2±6.7	10.8±5.8	<.001†
CSI										
Maximum CSI indicator dysphagia (%)					<.001*					<.001*
Unable to swallow solids	6.0	25.0	22.2	20.0		7.7	15.4	17.6	6.7	
Unable to swallow liquids	0.9	25.0	38.9	80.0		4.5	38.5	52.8	90.0	
Dysphagia NOS	34.2	50.0	38.9	0.0		56.9	46.2	27.5	3.3	
Normal swallowing	30.2	0.0	0.0	0.0		11.3	0.0	1.1	0.0	
Unknown/missing	28.6	0.0	0.0	0.0		19.6	0.0	1.1	0.0	
Admission CSI continuous score	15.4±9.7	16.8±9.1	24.4±13.3	34.6±11.5	<.001†	22.4±12.0	28.5±13.4	35.6±14.7	43.0±17.3	<.001†
Maximum CSI continuous score	22.2±12.9	26.0±16.6	41.1±17.3	56.2±30.5	<.001†	34.3±19.4	47.4±23.0	52.5±20.7	59.9±21.8	<.001†

NOTE. Values are mean ± standard deviation (SD) unless otherwise indicated.
Abbreviations: NOS, not otherwise specified; TIA, transient ischemic attack.
*Chi-square test.
†Analysis of variance (ANOVA).

Table 2: Process Variables for Moderate and Severe Strokes by Tube-Feeding Group

Process Variables	Moderate Stroke (CMGs 104–107)					Severe Stroke (CMGs 108–114)				
	No Tube Feeding (n=447)	Tube Feeding 1%–24% of Stay (n=4)	Tube Feeding ≥25% of Stay (n=18)	Tube Feeding 100% of Stay; Discharged With Tube Feeding (n=5)	Variation Significance (P)	No Tube Feeding (n=311)	Tube Feeding 1%–24% of Stay (n=13)	Tube Feeding ≥25% of Stay (n=91)	Tube Feeding 100% of Stay; Discharged With Tube Feeding (n=30)	Variation Significance (P)
Rehabilitation LOS	15.0±7.1	20.0±5.4	18.7±8.5	16.8±5.5	.079*	23.6±9.3	34.2±13.5	28.7±12.1	23.1±11.4	<.001*
PT										
No. of days	10.6±6.0	16.3±3.3	13.1±7.3	12.6±5.4	.085*	16.8±8.1	20.3±12.3	19.7±10.7	15.6±8.2	.018*
No. of minutes	665±384	950±256	704±398	622±404	.491*	1065±576	1204±949	1140±741	862±451	.016*
No. of min/patient/day	44.3±16.7	49.4±17.3	36.6±15.4	36.4±22.4	.162*	44.1±13.7	35.3±18.2	39.1±14.6	39.0±14.4	.003*
OT										
No. of days	9.2±5.8	13.3±4.7	12.3±6.8	10.4±9.3	.077*	14.5±8.0	16.7±12.0	16.9±10.5	13.9±7.7	.098*
No. of minutes	603±389	860±254	670±354	603±606	.530*	958±585	1088±869	1018±735	826±526	.441*
No. of min/patient/day	39.5±17.7	44.3±15.9	35.0±15.3	30.7±22.9	.454*	39.8±16.1	32.0±21.1	35.0±15.9	35.6±13.8	.025*
SLP										
No. of days	7.8±6.2	13.5±4.5	13.7±6.1	11.0±3.2	<.001*	13.7±8.4	18.8±10.0	18.2±10.8	14.4±9.8	<.001*
No. of minutes	396±355	656±291	755±374	564±152	<.001*	749±530	1107±710	1024±687	755±550	<.001*
No. of min/patient/day	24.7±16.2	32.4±11.2	38.4±12.3	34.9±10.6	.004*	30.8±15.8	31.6±13.4	34.1±14.2	32.5±15.2	.384*

NOTE. Values are mean ± SD.
*ANOVA.

(0%–1.8%), whereas the number of those tube feeding for 25% or more of stay ranged from 0% to 20.3% of a site's patients ($P<.001$). The number of patients discharged with tube feeding was very small in all sites, with only 5 patients in total.

The percentage of patients with severe stroke, who received tube feeding was statistically different by site ($P<.001$). Approximately 65% of patients in site 5 received tube feeding compared with 13% to 27% for the other sites. Over 17% of site 5 patients were discharged with tube feeding, which was double the percentage of the site with the second highest percentage. It is important to note that patients in site 5 had the lowest average admission total FIM score (lowest functioning) and the highest maximum CSI score (highest severity of illness), and the site had the second largest percentage of patients with severe stroke.[25]

Nutritional assessment methods of monitoring serum albumin and serum prealbumin levels and weight varied significantly by site ($P<.001$ for each). For patients with moderate strokes, the percentage of patients with more than 1 albumin level measurement varied by site from 5.4% to 34.3%; the percentage with no serum albumin measurements ranged from 20.6% to 81.3%. For patients with severe strokes, the variation by site for no serum albumin measurements ranged from 7.3% to 77.3%. No serum prealbumin measurements were recorded at sites 2 and 5. The number of patients with moderate strokes who were weighed more than once varied by site from 54.8% to 91.5%; it varied from 73.9% to 95.6% for patients with severe strokes. Two sites weighed all patients with severe strokes at least once (range of no weight measurements, 0%–21.7%).

Regression Analyses

Patients who received tube feeding for their entire rehabilitation stay and were discharged with tube feeding (group 4) were not included in OLS regression analyses, because they did not advance to oral intake or progressed little in other rehabilitation outcomes, as shown in table 3.

Tables 5 and 6 present significant variables in OLS regression analyses to predict the outcomes of increase in total FIM, motor FIM, and cognitive FIM scores and net medical improvement for patients with moderate and severe stroke. Patient characteristics and rehabilitation LOSs were controlled for in all analyses. Tube feeding for 1% to 24% of stay had only a borderline positive association ($P=.08$) with an increase in total FIM score in the moderate-stroke group and was not significant for the other outcomes (see table 5). For patients with severe stroke, tube feeding for 25% or more of stay had a significant positive association with each outcome; tube feeding for 1% to 24% of stay had a significant positive association with increase in total FIM and motor FIM scores only (see table 6).

DISCUSSION

One of the most telling findings in our study is the large site variation in nutritional assessment measures and use of tube feeding, which indicate that clinicians differ in the importance they place on nutrition as a stoke rehabilitation intervention. Because low functioning and higher severity of illness are associated with increased rates of tube feeding in our data, it is not surprising that site 5 had more patients who received tube feeding. However, sites 1, 2, and 3 had a similar mix of severe strokes (40%–68%) as site 5 (51%) but did not use tube-feeding interventions as frequently.

There does not appear to be an association between sites that have more patients with tube feeding and the measuring of serum albumin and prealbumin levels, because many patients

Table 3: Outcome Variables for Moderate and Severe Strokes by Tube-Feeding Group

Outcome Variables	Moderate Stroke (CMGs 104–107)					Severe Stroke (CMGs 108–114)				
	No Tube Feeding (n=447)	Tube Feeding 1%–24% of Stay (n=4)	Tube Feeding ≥25% of Stay (n=18)	Tube Feeding 100% of Stay; Discharged With Tube Feeding (n=5)	Variation Significance (*P*)	No Tube Feeding (n=311)	Tube Feeding 1%–24% of Stay (n=13)	Tube Feeding ≥25% of Stay (n=91)	Tube Feeding 100% of Stay; Discharged With Tube Feeding (n=30)	Variation Significance (*P*)
Improvement in nutritional status based on first and last albumin/prealbumin levels (must have >1 serum albumin/prealbumin measurement) (%)	4.0	0.0	11.1	20.0	.163*	4.5	15.4	8.8	16.7	.022*
Any mental disorder diagnosis (%)	51.7	50.0	61.1	60.0	.862*	53.4	61.5	51.7	60.0	.809*
Depression diagnosis (%)	9.0	25.0	27.8	20.0	.037*	12.2	30.8	22.0	16.7	.047*
Weight change (last − first) (kg)	−0.3±4.4	2.6±7.1	−0.4±4.9	2.2±6.2	.389†	−1.8±6.1	−0.4±3.1	−0.8±4.4	−0.9±4.6	.444†
Discharge total FIM score	98.6±11.6	96.3±9.9	98.4±15.2	68.4±28.8	<.001†	77.2±19.3	78.0±11.2	69.9±23.2	47.6±21.4	<.001†
Increase in total FIM score (discharge − admission)	26.1±9.7	34.8±13.0	30.5±15.2	4.2±23.7	<.001†	29.4±14.4	45.1±12.6	33.9±20.3	14.7±15.7	<.001†
Discharge motor FIM score	70.4±8.8	70.3±10.0	73.1±12.6	49.6±22.2	<.001†	53.5±14.6	57.9±10.8	49.6±18.5	33.6±16.6	<.001†
Increase in motor FIM score (discharge − admission)	22.4±8.2	27.8±10.6	25.0±12.1	3.4±20.1	<.001†	24.5±12.3	36.6±13.0	26.9±16.8	11.7±13.1	<.001†
Discharge cognitive FIM score	28.2±5.9	26.0±7.4	25.1±6.1	18.8±10.0	<.001†	23.7±7.0	20.1±5.5	20.2±7.6	13.9±7.4	<.001†
Increase in cognitive FIM score (discharge − admission)	3.6±3.6	7.0±2.5	5.7±4.5	0.8±4.6	.009†	4.9±4.3	8.5±2.7	7.0±5.1	3.1±4.4	<.001†
Discharge CSI continuous score	5.5±6.3	6.25±2.6	10.8±6.8	26.4±13.8	<.001†	11.8±11.6	13.6±10.3	16.7±11.5	30.6±17.0	<.001†
Increase in severity (maximum − admission CSI score)	6.8±7.3	9.3±8.1	16.6±10.9	21.6±19.7	<.001†	11.9±11.4	18.8±18.3	16.8±12.4	16.9±13.7	.001†

Table 3: (Cont'd) Outcome Variables for Moderate and Severe Strokes by Tube-Feeding Group

Outcome Variables	Moderate Stroke (CMGs 104–107)					Severe Stroke (CMGs 108–114)				
	No Tube Feeding (n=447)	Tube Feeding 1%–24% of Stay (n=4)	Tube Feeding >25% of Stay (n=18)	Tube Feeding 100% of Stay; Discharged With Tube Feeding (n=5)	Variation Significance (*P*)	No Tube Feeding (n=311)	Tube Feeding 1%–24% of Stay (n=13)	Tube Feeding >25% of Stay (n=91)	Tube Feeding 100% of Stay; Discharged With Tube Feeding (n=30)	Variation Significance (*P*)
Net medical improvement (admission − discharge CSI score)	9.9±8.0	10.5±10.5	13.6±11.3	8.2±5.2	.282†	10.6±9.3	14.9±7.3	18.9±11.3	12.4±10.3	<.001†
Pneumonia diagnosis (%)	1.8	0.0	5.6	20.0	.028*	5.5	15.4	22.0	20.0	<.001*
Discharge destination (%)					.307*					<.001*
Community discharge including home	95.1	100.0	100.0	80.0		77.8	69.2	68.1	43.3	
Inpatient institutional discharge	4.9	0.0	0.0	20.0		22.2	30.8	31.9	56.7	

NOTE. Values are mean ± SD unless otherwise indicated.
*Chi-square test.
†ANOVA.

Table 4: Site Variation in Nutrition Process Variables

Facility Processes	Moderate Stroke (CMGs 104–107)							Severe Stroke (CMGs 108–114)						
	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	*P*	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	*P*
Patients (n)	73	91	47	112	59	92		82	66	119	46	91	41	
Enteral tube feeding (%)							<.001*							<.001*
No tube feeding	97.3	100.0	95.7	95.5	72.9	97.8		75.6	84.9	76.5	87.0	35.2	73.2	
Tube feeding 1%–24% of stay	1.4	0.0	0.0	1.8	1.7	0.0		4.9	3.0	2.5	2.2	2.2	2.4	
Tube feeding ≥25% of stay	1.4	0.0	4.3	0.9	20.3	2.2		18.3	9.1	16.8	2.2	45.1	19.5	
Tube feeding 100% of stay and discharged with tube feeding	0.0	0.0	0.0	1.8	5.1	0.0		1.2	3.0	4.2	8.7	17.6	4.9	
Serum albumin measurements (%)							<.001*							<.001*
0	20.6	73.6	72.3	81.3	44.1	78.3		7.3	77.3	54.6	54.4	31.9	56.1	
1	45.2	18.7	21.3	13.4	39.0	16.3		39.0	18.2	30.3	34.8	36.3	22.0	
>1	34.3	7.7	6.4	5.4	17.0	5.4		53.7	4.6	15.1	10.9	31.9	22.0	
Serum prealbumin measurements (%)							<.001*							<.001*
0	84.9	100.0	100.0	97.3	100.0	82.6		68.3	100.0	90.8	91.3	100	61.0	
1	13.7	0.0	0.0	2.7	0.0	15.2		29.3	0.0	7.6	8.7	0.0	22.0	
>1	1.4	0.0	0.0	0.0	0.0	2.2		2.4	0.0	1.7	0.0	0.0	17.1	
Weight measurements (%)							<.001*							<.001*
0	5.5	5.5	10.6	20.5	0.0	8.7		4.9	0.0	6.7	21.7	0.0	4.9	
1	39.7	14.3	29.8	13.4	8.5	23.9		17.1	4.6	24.4	4.4	4.4	19.5	
>1	54.8	80.2	59.6	66.1	91.5	67.4		78.1	95.5	68.9	73.9	95.6	75.6	
Mean no. of weight measurements ± SD	2.1±1.1	2.7±1.4	2.1±1.1	2.9±1.8	5.2±4.9	3.1±3.1	<.001†	2.7±1.2	4.6±2.1	2.7±1.5	3.5±1.8	8.7±7.6	4.1±4.0	<.001†

*Chi-square test.
†ANOVA.

Table 5: Improving Outcomes: Regression Analysis Results for Moderate Stroke (CMGs 104–107)*

	Dependent Variables											
	Increase Total FIM Score			Increase Motor FIM Score			Increase Cognitive FIM Score			Net Medical Improvement (Admission − Discharge CSI)		
Independent Variables	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*
Tube feeding 1%–24% of stay	3.991	3.1	.080									
Partial R^2		.006										
Tube feeding ≥25% of stay												
Partial R^2												
Age	−0.174	35.5	<.001	−0.147	35.0	<.001	−0.020	4.5	.035			
White	1.774	4.3	.039	1.549	4.4	.036						
Other race										1.360	4.2	.042
Incomplete low paraplegia or worse/ complete hemiplegia	−3.605	4.6	.032				−1.386	6.5	.011			
Incomplete hemiplegia										3.073	22.9	<.001
Stroke location: brainstem/cerebellum										1.442	6.6	.010
Comorbidity diabetes							0.629	4.1	.043			
Admission motor FIM score	−0.493	37.0	<.001	−0.474	47.5	<.001						
Admission cognitive FIM score	−0.247	16.1	<.001				−0.307	224.0	<.001			
Admission CSI score							−0.039	7.1	.008	0.657	778.4	<.001
Rehabilitation LOS	−0.223	12.3	<.001	−0.225	17.8	<.001						
R^2		.186			.148			.357			.627	

Abbreviation: Coeff, coefficient.
*n=469.

with low albumin or prealbumin levels were not tube fed. Albumin and prealbumin values were obtained by retrospective chart review. A portion of site variability could be due to results not being reported clearly or documented in the chart at the time of review. In addition, other measures may have been used to assess nutritional risk, and clinicians may question whether high nutritional risk, as defined by low albumin or prealbumin level, is sufficient to initiate tube feeding. Studies

Table 6: Improving Outcomes: Regression Analysis Results for Severe Stroke (CMGs 108–114)*

	Dependent Variables											
	Increase Total FIM Score			Increase Motor FIM Score			Increase Cognitive FIM Score			Net Medical Improvement (Admission − Discharge CSI)		
Independent Variables	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*	Coeff	F	*P*
Tube feeding 1%–24% of stay	13.290	9.8	.002	12.225	12.1	.006						
Partial R^2		.013			.018							
Tube feeding ≥25% of stay	5.424	8.2	.005	4.497	8.4	.004	1.335	6.8	.009	3.567	11.0	.001
Partial R^2		.011			.013			.008			.012	
Age	−0.337	39.5	<.001	−0.332	55.3	<.001	−0.044	9.1	.003			
Incomplete low paraplegia or worse/complete hemiplegia	−9.127	20.8	<.001	−7.419	19.5	<.001				−2.997	7.8	.005
Incomplete hemiplegia												
Monoplegia UE/complete monoplegia LE/normal				4.902	4.4	.037						
Stroke type: hemorrhagic							−1.126	6.5	.011	2.262	6.2	.013
Stroke side: right							0.861	4.8	.029			
Stroke side: left				3.370	7.2	.008						
Comorbidity diabetes	−4.790	9.8	.002	−3.695	8.3	.004	−1.256	9.5	.002	−1.781	4.4	.038
BMI underweight (<18.5kg/m^2)										4.556	4.2	.042
Admission motor FIM score	0.249	4.4	.038				0.097	7.6	.006	0.187	6.6	.011
Admission cognitive FIM score				0.329	14.6	<.001	−0.288	87.1	<.001	0.136	4.7	.031
Admission CSI score							−0.044	6.7	.010	0.427	143.5	<.001
Rehabilitation LOS	0.210	7.6	.006				−1.344	6.5	.011	0.157	14.8	.001
R^2		.201			.206			.301			.405	

Abbreviations: LE, lower extremity; UE, upper extremity.
*n=415.

have shown that malnutrition is associated with poorer outcomes, so it would seem that nutrition and nutritional assessment measures would be a standard of care implemented with similar frequencies across not only hospital organizations but also in all other health care–providing institutions. However, in our sample of rehabilitation centers, this is not the case.

A possible reason for the disparity in tube feeding is the lack of data showing benefits of nutrition or tube feeding in stroke rehabilitation. Dávalos et al[3] found that nutritional status declined despite adequate enteral feeding after acute stroke. Dávalos concluded that caloric intake was not the only factor affecting malnutrition; therefore, the impact of nutritional intervention on stroke outcomes remained unclear.

Other articles suggest that the unclear relation may be due to the fact that serum albumin level, which usually is used in the definition of nutritional status, also is associated with underlying disease processes.[24,27] To minimize reliance on interpretation of albumin level, we related amount of tube feeding to rehabilitation outcomes directly. Tube feeding is associated with improved rehabilitation outcomes for patients with severe strokes, although not for patients with moderate strokes. One reason an effect may not have been detected in the moderate-stroke group is the small number of patients who received tube feeding—22 of 469 (4.7%) compared with 104 to 415 (25.1%) patients with severe stroke (omitting patients discharged with tube feeding). Intuitively, if tube feeding is beneficial for patients with severe strokes, it should be beneficial for patients with moderate strokes when deemed necessary by clinical staff.

One problem with tube feeding is the perceived risk of aspiration that may lead to mild symptoms, such as small increases in white blood cell count, higher temperatures, and lethargy or more severe symptoms associated with pneumonia.[28] These symptoms may decrease a patient's ability to participate fully in therapy, thus affecting outcomes. The challenge with assessing aspiration risk is knowing what caused the aspiration. Feeding tubes often are placed when patients are at risk for aspiration, but as their swallowing improves, they begin therapeutic oral feedings while continuing tube feeding. Our data were not collected in a manner that would allow us to differentiate reasons for aspiration in these types of patients, so the cause-and-effect association of tube feeding and aspiration would he difficult to interpret. This limits our ability to understand if the improvement in outcomes associated with tube-fed patients is related to nutrition or to the reduction of adverse aspiration signs and symptoms that negatively affect therapy. However, tube-fed patients with moderate and severe strokes did have a significantly larger increase in severity of illness (maximum and admission CSI) and did have a pneumonia diagnosis code significantly more often during rehabilitation than patients who were not tube fed. We did not determine if pneumonia was diagnosed before or after tube placement. The general rule is that sicker patients have poorer outcomes, but this did not hold in our sample. It appears that tube feeding provided enough of a benefit to counteract the negative effects of aspiration that may cause greater increase in severity of illness and more pneumonia, leading to the assumption that nutrition is an intervention that improves outcomes.

The PSROP provided a first look at how nutrition may be an important component of stroke rehabilitation. The primary objective of this article was to describe and test our hypothesis that nutrition risk assessment and use of tube feeding is associated with better outcomes for patients with moderate and severe strokes. Our data indicate that use of tube feeding is associated with greater increases in function and decreases in severity of illness for patients with severe strokes, but clearly further examination is warranted.

CONCLUSIONS

This study identifies nutritional support (tube feeding) as an effective therapy in stroke rehabilitation. Use of nutritional intervention was associated with greater motor and cognitive improvements in the most severely impaired patients. The high level of site variation in the use of nutritional assessments and interventions for patients with stroke speaks loudly to the need for additional study of the role of nutrition as an important component of stroke rehabilitation. Further study, including a consistent measure of nutritional status during the rehabilitation stay, seems warranted.

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ORIGINAL ARTICLE

The Early Impact of the Inpatient Rehabilitation Facility Prospective Payment System on Stroke Rehabilitation Case Mix, Practice Patterns, and Outcomes

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ABSTRACT. DeJong G, Horn SD, Smout RJ, Ryser DK. The early impact of the inpatient rehabilitation facility prospective payment system on stroke rehabilitation case mix, practice patterns, and outcomes. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S93-100.

Objective: To determine the early effects of the inpatient rehabilitation facility (IRF) prospective payment system (PPS) on stroke rehabilitation case mix, practice patterns, and outcomes.

Design: Prospective observational cohort study.

Setting: Three IRFs in the United States.

Participants: Consecutively enrolled convenience sample of 539 stroke rehabilitation patients treated between 2001 and 2003 in 3 IRFs.

Interventions: Not applicable.

Main Outcome Measures: Length of stay (LOS), therapy utilization, FIM instrument gain, and discharge destination.

Results: The IRF-PPS had no material short-term effect on stroke rehabilitation case mix and LOS for the study facilities. Facilities shifted physical and occupational therapy resources from those in the most severe case-mix groups (CMGs) to those in the moderate CMGs. Those in the more severe CMGs also experienced a noticeable decline in FIM score gain over the course of the rehabilitation stay. Using multivariate analyses, the authors discerned no major role for the IRF-PPS in explaining pre- and post-PPS differences in utilization and outcome among study facilities.

Conclusions: For the 3 study facilities, IRF-PPS did not materially reshape stroke rehabilitation case mix, utilization, and outcome in the early stages of PPS implementation, apart from the shift in therapy resources from more severely involved stroke patients to moderately involved patients. The study's findings are limited to 3 facilities, and a longer time horizon is needed to more fully determine the effects of the IRF-PPS.

Key Words: Prospective payment system; Rehabilitation.

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INPATIENT REHABILITATION FACILITIES (IRFs) are a major venue for poststroke rehabilitation, and patients with stroke are the second-largest group of people served by IRFs, accounting for nearly 20% of all IRF discharges.[1] For better or for worse, payment systems are major drivers of poststroke rehabilitation care. The largest payer for inpatient rehabilitation care remains the Medicare program. Medicare pays for 65% of all IRF-level stroke care in the United States (Sam Fleming, eRehabData.com, personal communication, August 2, 2005), and its payment systems shape access, utilization, and costs of IRF-level care. In 2002, the Centers for Medicare and Medicaid Services (CMS) implemented a prospective payment system (PPS) for IRFs. Using in-depth stroke rehabilitation data from 3 IRFs across the nation, this article provides a preliminary assessment of the early impact of the IRF-PPS on stroke rehabilitation case mix, practice patterns (ie, length of stay [LOS], service mix, intensity), and short-term outcomes (ie, functional status, discharge disposition).

Background

The IRF-PPS had been a long time in coming. When Congress initiated the Medicare diagnosis-related group (DRG)–based PPS for short-stay acute care hospitals in 1983, it exempted specialty hospitals (ie, rehabilitation centers, children's hospitals, psychiatric hospitals, long-term care hospitals) and various postacute venues (eg, skilled nursing facilities [SNFs], home health agencies) from a PPS. Congress left these facilities to be paid on a modified cost basis as provided by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA). Both Medicare DRGs and cost-based reimbursement for postacute care led to a rapid expansion of postacute facilities of all types from the mid 1980s to the mid 1990s. In 1997, Congress passed the Balanced Budget Act of 1997 to curb this growth by authorizing the Health Care Financing Administration to establish PPSs for IRFs, SNFs, and home health agencies. Congress later authorized a PPS for long-term care hospitals in the Balanced Budget Refinement Act of 1999 (BBRA 1999). When implementing these legislative mandates, CMS instituted different PPS methods for each postacute setting with different start dates and phase-in periods.

This article examines the early impact of the IRF-PPS on stroke rehabilitation patients, practices, and outcomes. More specifically, it examines the impact on stroke case mix (patient severity, case-mix groups [CMGs]); functional status; severity index; utilization (ie, LOS); the mix, duration, and intensity of therapy services; and outcomes at discharge (ie, functional status, discharge destination). It does not attempt to evaluate the indirect effects of other postacute PPSs on IRF-based stroke rehabilitation. Other postacute PPSs shape the willingness of various postacute providers to enter or exit the stroke rehabilitation market and their willingness to accept certain types of patients and thus indirectly shape the case-mix and practice patterns observed among IRFs. At this early stage, we do not have a clear picture of how the IRF-PPS is shaping stroke rehabilitation care and its

Table 1: Stroke CMGs and CMG Groupings by Relative Tier Weights

Stroke CMG Groupings	CMG	Stroke CMG Definition			Relative Weights			
		Motor FIM Score	Cognitive FIM Score	Age (y)	Tier 1	Tier 2	Tier 3	None
Mild (CMG 101–103)	0101	69–84	23–35		0.478	0.428	0.408	0.386
	0102	59–68	23–35		0.651	0.583	0.555	0.526
	0103	59–84	5–22		0.830	0.743	0.708	0.670
Moderate (CMG 104–107)	0104	53–58			0.901	0.807	0.769	0.728
	0105	47–52			1.134	1.016	0.968	0.916
	0106	42–46			1.395	1.249	1.191	1.127
	0107	39–41			1.616	1.447	1.379	1.305
Severe (CMG 108–114)	0108	34–38		≥83	1.748	1.565	1.492	1.412
	0109	34–38		<83	1.890	1.693	1.613	1.527
	0110	12–33		≥89	2.028	1.816	1.730	1.638
	0111	27–33		82–88	2.089	1.871	1.783	1.687
	0112	12–26		82–88	2.478	2.220	2.115	2.002
	0113	27–33		<82	2.238	2.004	1.910	1.807
	0114	12–26		<82	2.730	2.445	2.330	2.205

Source: Centers for Medicare and Medicaid Services.[6]

outcomes. We do know anecdotally that many IRFs have made adjustments in their programs in the wake of the IRF-PPS, but we do not know how they have adjusted their programs and the effects that these adjustments may have had on the nature of stroke care and its outcomes.

Design of the IRF-PPS

CMS initially sought to implement a per diem PPS known as resource utilization groups for IRFs as it had in the SNF industry. Instead, with the passage of the BBRA 1999, the IRF industry prevailed on Congress to have CMS implement a per-discharge PPS known as function-related groups (FRGs) based on each patient's functional profile on admission to rehabilitation. In other words, Medicare would pay IRFs a fixed amount per discharge or per case based mainly on each patient's functional status at admission.

The FRG approach was originally developed by Stineman et al[2] with industry backing in the early to mid 1990s. Using rehabilitation LOS as a proxy for resource utilization, Stineman attempted to determine for each impairment group, such as stroke, those patient characteristics (eg, functional status [as measured by the FIM instrument], age) that best explained variation in LOS. Based on the results of this work, the initial FRG system classified rehabilitation patients into 1 of 53 distinct groups according to each patient's impairment (eg, stroke), functional status (eg, FIM motor score), and—in some instances—age. Subsequent refinements undertaken by Stineman et al,[3] the Rand Corporation,[1,4,5] and CMS[6] eventually led to a 95-group classification system now referred to as CMGs. At the time of this study, there were 14 CMGs for stroke rehabilitation based on a patient's motor or cognitive FIM scores on admission, and in 7 CMGs, the patient's age is also taken into account (table 1).[7]

One of the later additions to the patient classification system for the IRF-PPS was an adjustment for comorbidities. Providers argued that their patients presented a host of comorbidities that affected resource utilization, as did each patient's functional status. In short, they argued that the function-based classification system overlooked the medical acuity and comorbidities that also drive resource utilization. The Health Care Financing Administration (now CMS) responded and had its principal contractor, Rand, take another look. Rand found that adding comorbidities did help explain additional variance in resource utilization. The final rule implementing the new PPS ranks each comorbidity according to 1 of 3 tiers of severity specific to each patient's main impairment (eg, stroke). Thus, each CMG comes with 4 weights—3 for different levels of comorbidity severity and a fourth for no comorbidities.[6] The CMG weight assigned to each patient depends on the most severe comorbidity the patient presents. Although comorbidities are factored into the new PPS, there is uncertainty, if not controversy, about the current approach used to capture this dimension of patient need.

In addition to the function-based and comorbidity-modified patient classification system, the IRF-PPS also makes adjustments for (1) transfers—patients who are transferred from an IRF to other settings of care, (2) outliers—patients who have exceptionally long LOSs, and (3) interrupted stays—patients whose stay in an IRF is interrupted because of an acute condition that may require a temporary stay in an acute care hospital.

The IRF-PPS also makes adjustments in the per-case payment amount for market- and facility-level characteristics: (1) local wage rates—the payment system adjusts for the relative cost of labor in a given metropolitan statistical area; (2) rural status—the payment system provides an additional 19.14% payment for IRFs located in rural areas; and (3) low-income patient adjustment—the payment system provides additional payment for IRFs serving a disproportionate number of low-income patients.

Before these adjustments, the base rate for an average case in fiscal year 2004 was $12,525. In CMS parlance, this is known as the "conversion factor"—that is, the factor that is converted to a payment amount based on CMG-comorbidity weight, local wage adjustment, rural status, and low-income adjustment.

Impact of the IRF-PPS

Although considerable research work has been expended on the design of the IRF-PPS, comparatively little research has been published on the probable or actual impact of the IRF-PPS on access, case mix, utilization, costs, outcomes, and other issues such as provider equity, efficiency, financial performance, and gaming. Before IRF-PPS implementation, considerable work was done by both researchers and providers to estimate the probable financial impact of the IRF-PPS using simulation analyses and other techniques.[8] The chief limitation of this work is that investigators assumed that provider behav-

Table 2: Study Group Enrollment Pre- and Post-PPS

IRF	Pre-PPS	Post-PPS	Total*
A	79	78	157
B	58	133	191
C	98	93	191
Total	235	304	539

*Of the 567 patients, 28 had insufficient data (eg, incomplete FIM data) to assign them to a CMG. Thus, the total enrollment for purposes of this analysis is 539 patients.

ior would remain constant and that case-mix and practice patterns would therefore remain static.

It will be years before the many direct and indirect effects of the IRF-PPS on stroke rehabilitation can be fully observed, as we have learned from the implementation of the DRG-based PPS for short-term acute care hospitals. Providers will continue to make adjustments in stroke rehabilitation as they learn from their experiences during the first several years of implementation. Given the IRF-PPS implementation in 2002, there has been little time to report the new payment's impacts. This article provides an early window into the ways in which a geographically diverse group of 3 stroke rehabilitation providers have altered their case-mix and practice patterns and how these have affected utilization and short-term outcomes.

METHODS

The methodology governing the full PSROP, provided in this supplement by Gassaway et al,[9] provides a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, and a detailed description of the project's final study group. The methodology is summarized in by Maulden et al.[10] The institutional review boards at Boston University and at each participating IRF approved the study.

Methods That Pertain to the Analysis of the Impact of the IRF-PPS

The PSROP offers a rare opportunity to examine the early impacts of the IRF-PPS, because patients were enrolled both before and after the implementation of the IRF-PPS in 2002. Three of the 6 facilities enrolled a substantial number of patients with stroke both before and after the implementation of the IRF-PPS. Hence, this analysis is limited to just these 3 facilities. The other 3 facilities enrolled patients predominately before or after the implementation of the IRF-PPS and we chose to exclude these facilities because they did not provide an adequate before-and-after view of how the case mix, practice patterns, and outcomes changed with the implementation of the IRF-PPS at these facilities.

Table 2 outlines the study group size and enrollment before and after the implementation of the IRF-PPS at each of the 3 facilities. These 3 facilities enrolled 567 stroke rehabilitation patients. Of this number, 28 patients had some missing FIM data and therefore could not he classified into 1 of the 14 stroke CMGs. We excluded these 28 patients, leaving a total of 539 patients included in this analysis (see table 2).

The 3 IRF facilities provide some geographic diversity—1 on the East Coast, 1 on the West Coast, and 1 in the middle of the United States. All 3 facilities were rehabilitation units in academic health centers.

Pre- and Post-PPS Periods

The IRF-PPS sought to bring greater equity among IRFs that previously had received widely varying levels of reimbursement under the old TEFRA system and to foster access for potential rehabilitation patients by tailoring the amount of payment to the functional and medical needs of each patient. In presenting our results below, we compare findings in the post-PPS period with those from the pre-PPS period. All 3 IRFs also had a ramp-up period before the IRF-PPS implementation date. This ramp-up period varied from 1 to 6 months. We speculated that IRF behavior with respect to admissions and processes of care might already have started to change during this ramp-up period. Accordingly, we considered 3 time periods for analyses: (1) a pre-PPS period, (2) a post-PPS period, and (3) a practice period in preparing for the IRF-PPS implementation. On closer examination of the data, we determined that nearly all patient and practice parameters during the practice or ramp-up period were nearly the same as those during the pre-PPS period and that the most marked changes, where they were discernable, occurred with the implementation of the PPS—that is, during the post-PPS period. Thus, we folded the ramp-up or practice period into the pre-PPS period and present our results below for only 2 periods, the pre-PPS period and the post-PPS period.

Medicare and Non-Medicare

The IRF-PPS applies only to stroke patients with Medicare and not to patients covered by other types of health plans. Medicare is the major driver of rehabilitation practice and its requirements and effects are known to spill over to patients covered by other health plans. We tested for Medicare and non-Medicare differences with respect to practice patterns and did not detect sufficient differences to exclude non-Medicare patients from the analyses presented below.

Two-Way, 3-Way, and Multivariate Analyses

In the results that follow, we examine the changes—pre- and post-PPS—across study group characteristics, medical and functional status, service utilization, and outcomes. In most instances, we added a third dimension to the analyses when examining changes from pre- to post-PPS—namely, the CMG groupings—to help account for case-mix differences. To simplify matters, we grouped patients into mild, moderate, and severe groupings (table 1).

Even in 2-way and 3-way analyses, there may be differences that can be explained only when all potential independent variables are considered concurrently. Thus, we used both ordinary least-squares (OLS) and logistic regression analyses to help explain differences in utilization and outcomes in the pre- and post-PPS periods. We sought to control for patient differences to determine how much of the variance could be explained by the IRF-PPS. We used a stepwise procedure that ceased when no other variables met the .08 level of significance for entry into the model.

One of the challenges in the regression analyses was how to capture the IRF-PPS in our regression models. We took 2 approaches. First, we used a simple dichotomous pre- and post-PPS variable. Second, we considered each facility's TEFRA limit before PPS. We hypothesized that the effect of the IRF-PPS on utilization and outcome would, in part, be a function of the IRF's pre-PPS TEFRA limit—that is, we had to take into account how high or how low the TEFRA limit was relative to the expected payment under PPS. To do so, we adjusted each facility's TEFRA limit by the CMS wage index to account for differences in labor purchasing power across market areas. We applied the CMS wage index to both the labor share of the TEFRA limit and to the entire TEFRA limit, and in both cases, the results were essentially the same: 1

Table 3: Study Group Characteristics Pre- and Post-PPS Enrollment

Patient Characteristics	Pre-PPS (n=235)	Post-PPS (n=304)	Total* (N=539)	P
Mean age (y)	66.0	65.7	65.8	.828†
Sex (% male)	50.6	50.7	50.7	1.00‡
Race (%)				.214‡
White	60.1	62.2	61.2	
Black	26.8	21.1	23.6	
Other (including Hispanic)	13.2	16.8	15.2	
Payer (%)				.016‡
Medicare	51.9	55.3	53.8	
Other	48.1	42.8	45.1	
Unknown or missing		2.0	1.1	
Type of stroke (%)				.479‡
Hemorrhagic	22.6	25.3	24.1	
Ischemic	77.5	74.7	75.9	
Mean admission FIM score	62.4	61.0	61.6	.465†
CMG (%)				.093‡
Mild (CMG 101–103)	8.1	13.8	11.3	
Moderate (CMG 104–107)	49.4	43.8	46.2	
Severe (CMG 108–114)	42.6	42.4	42.5	
CMI	1.39	1.42	1.41	.613†
Mean admission CSI§	20.1	21.9	21.1	.142†
Mean days from stroke onset to rehabilitation	10.9	10.7	10.7	.822†

Abbreviation: CMI, case-mix index.
*Of the 567 patients, 28 had insufficient data (eg, incomplete FIM data) to assign them to a CMG. Thus, the total enrollment for purposes of this analysis is 539 patients.
†The *t* test.
‡Chi-square test.
§Comprehensive Severity Index (CSI) expressed here as a continuous variable.

facility had a high adjusted TEFRA limit and 2 of the facilities had low adjusted TEFRA limits relative to their expected payment under PPS. In our model, we hypothesized that facilities having a high adjusted TEFRA limit, for example, had the financial wherewithal to provide a richer mix of therapy, offer longer LOSs, and with additional inputs, produce better outcomes in the pre-PPS period.

RESULTS

Study Group Characteristics and Impact on Stroke Case Mix

Table 3 describes the 3-facility study group's principal characteristics in terms of age, sex, race, type of stroke, payer mix, and each group's medical and functional profile. By tailoring the level of payment to the functional status and medical complexity of each patient with stroke on admission, the IRF-PPS was designed to encourage IRFs to admit patients based on the functional and medical needs of each patient with stroke. The old pre-PPS, it was thought, encouraged IRFs to admit less complex patients to maximize financial margins.

There are 2 ways to examine whether the IRF-PPS encouraged the 3 IRFs to admit patients with stroke with greater functional needs. The first is to examine pre- and post-PPS functional status, as measured by the FIM score at admission. We found that the 3 IRFs combined admitted only marginally more functionally dependent patients with stroke as measured by FIM score at admission. The second is to consider the pre- and post-PPS case-mix distributions by CMG. In this case, we grouped the stroke CMGs into mild (CMG 101–103), moderate (CMG 104–107), and severe (CMG 108–114) groups. Among the 3 facilities represented here, there was a modest shift from the moderate CMG group to the mild CMG group, and the percentage of those in the severe group remained about the same at about 42.5%.

One way to examine whether the IRF-PPS encouraged the 3 IRFs to admit those patients with stroke who had more complex medical needs is to evaluate the pre- and post-PPS patient scores on the Comprehensive Severity Index (the continuous version) at admission. We found that the 3 facilities served a slightly more (but statistically insignificant) medically complex group of patients with stroke in the post-PPS period than they did in the pre-PPS period.

A facility's case-mix index (CMI) captures, to some degree, both the functional and medical needs of its patients by considering each patient's CMG assignment (CMG 101–114) and each patient's tier level assignment within each CMG that takes into account the presumed severity of that patient's comorbidities. Both a patient's CMG assignment and tier assignment determine that patient's case weight (see table 1). Averaging all patient case weights determines a facility's or group's CMI, with a higher CMI indicating a more severe case mix. For the study group representing all 3 facilities, we found the CMI relatively unchanged from the pre-PPS period (CMI=1.39) to the post-PPS period

Table 4: Mean LOS by Stroke CMG Pre- and Post-PPS

Stroke CMG	Pre-PPS (d)	Post-PPS (d)	Change (d)	P*
Mild (CMG 101–103)	7.1	7.8	0.7	.665
Moderate (CMG 104–107)	13.5	14.9	1.4	.158
Severe (CMG 108–114)	25.2	24.1	−1.1	.496
Total	17.9	17.8	−0.1	.909

*The *t* test.

Table 5: Amount of Rehabilitation Therapy Received by Stroke CMG Pre- and Post-PPS

Therapy by Stroke CMG	Pre-PPS	Post-PPS	Change	P*
PT				
Mild (CMG 101–103)				
Mean min of PT	289.7	267.9	−21.8	.716
Mean LOS (d)	7.1	7.8	0.7	.665
Mean days of PT	5.0	4.8	0.2	.870
Mean min of PT/d	45.2	35.1	−10.1	.084
Moderate (CMG 104–107)				
Mean min of PT	547.7	645.0	97.3	.072
Mean LOS (d)	13.5	14.8	1.3	.158
Mean days of PT	8.3	10.0	1.7	.031
Mean min of PT/d	39.8	43.4	3.6	.160
Severe (CMG 108–114)				
Mean min of PT	1086.0	894.2	−191.8	.017
Mean LOS (d)	25.2	24.1	−1.1	.496
Mean days of PT	17.2	15.6	−1.6	.214
Mean min of PT/d	42.2	37.5	−4.7	.027
Total				
Mean min of PT	755.8	698.7	−57.1	.240
Mean LOS (d)	17.9	17.8	−0.1	.909
Mean days of PT	11.8	11.7	−0.1	.882
Mean min of PT/d	41.3	39.7	−1.6	.336
OT				
Mild (CMG 101–103)				
Mean min of OT	207.4	259.9	52.5	.428
Mean LOS (d)	7.1	7.8	0.7	.665
Mean days of OT	3.7	4.2	0.5	.672
Mean min of OT/d	28.8	34.8	6.0	.240
Moderate (CMG 104–107)				
Mean min of OT	474.3	568.1	93.8	.067
Mean LOS (d)	13.5	14.8	1.3	.158
Mean days of OT	7.1	8.7	1.6	.033
Mean min of OT/d	34.7	36.3	1.6	.498
Severe (CMG 108–114)				
Mean min of OT	986.2	782.1	−204.1	.009
Mean LOS (d)	25.2	24.1	−1.1	.496
Mean days of OT	15.2	13.6	−1.6	.198
Mean min of OT/d	38.3	33.3	−5.0	.019
Total				
Mean min of OT	670.5	616.3	−54.2	.243
Mean LOS (d)	17.9	17.8	−0.1	.909
Mean days of OT	10.3	10.2	−0.1	.918
Mean min of OT/d	35.8	34.8	−1.0	.531

*The *t* test.

(CMI=1.42). We also found little change within each of the 3 facilities represented in the study.

Impact on the Utilization and Provision of Stroke Rehabilitation Services

The IRF-PPS provides incentives for IRFs to review their practice patterns and processes of care relative to the resources that will be available for each stroke patient given their CMGs and tier assignments. To ascertain the steps taken at each facility with respect to the process of care, we queried each facility's lead stroke physician. They reported that they made no changes in admission criteria nor did they attempt to achieve a particular case mix. This is confirmed by the results noted above. The stroke physicians reported that they did not establish target LOSs based on PPS apart from the way in which they had always estimated expected LOS in the pre-PPS period. A couple reported that the projected LOS for each CMG gave them an additional benchmark by which to estimate an expected LOS. The 3 facilities already had formal or informal clinical pathways for stroke rehabilitation and did not revisit them in the wake of the IRF-PPS implementation. As a result, they reported no deliberate attempt to alter therapy frequency or intensity.

This said, the facilities reported that they did take steps to evaluate certain care processes, particularly at the front and back ends of a patient's stay. If they had not already done so, facilities sought to shorten the evaluation and assessment processes to make sure that therapy commenced more quickly and by day 2 whenever possible. At the back end, a patient's discharge can sometimes be delayed, for example, because of lack of equipment or arrangements at the target destination. Facilities reported that they made attempts to regularly review potential barriers to discharge and to address these barriers well in advance of the projected discharge date. In short, our respondents indicated that the changes were more administrative than clinical.

Table 6: Change in Functional Status from Admission to Discharge, Pre- and Post-PPS

Stroke CMG	Pre-PPS	Post-PPS	Change	P*
Mild (CMG 101–103)				
Admission FIM	94.7	89.3	−5.4	.039
Discharge FIM	108.7	109.1	0.4	.880
Increase in FIM	14.0	19.8	5.8	.015
Moderate (CMG 104–107)				
Admission FIM	72.4	71.5	−0.9	.503
Discharge FIM	99.8	96.9	−2.9	.090
Increase in FIM	27.3	25.4	−1.9	.231
Severe (CMG 108–114)				
Admission FIM	44.6	41.1	−3.5	.033
Discharge FIM	78.7	69.3	−9.4	.033
Increase in FIM	33.3	28.2	−5.1	.049
Total				
Admission FIM	62.4	61.0	−1.4	.465
Discharge FIM	91.8	87.0	−4.8	.015
Increase in FIM	28.7	25.8	−2.9	.034

*The *t* test.

Impact on LOS

For the 3 facilities combined, there was virtually no change in overall LOS from the pre- to the post-PPS period. The only marked change was at 1 facility that saw a 3-day decline in LOS, in part due to an increase in patients in the mild CMG group (101–103). Table 4 provides a breakdown in the changes in LOS by CMG. The largest increase, although not statistically significant, in LOS was among patients in the moderate CMG group. As observed in the next section, this group also had the largest increase in therapy time.

Impact on the Amount, Intensity, and Duration of Physical and Occupational Therapy Services

Table 5 characterizes the amount, duration, and intensity of therapy rendered. We could not report utilization of speech and language therapy because of incomplete data at one of the 3 facilities. We found that the 3 facilities provided somewhat less physical therapy (PT) and occupational therapy (OT) from the pre- to the post-PPS periods but not to any statistically significant degree.

More important is the very noticeable shift in both PT and OT services from those in the more severe CMGs (108–114) to those in the moderate CMGs (104–107). This is the opposite of what was intended under the IRF-PPS, which seeks to provide a more level playing field across all patients by tailoring the amount of payment to the medical and functional needs of each individual patient. Clearly, this is not case here, where we see a shift in resources from more severely impaired patients to more moderately impaired patients. This finding is what one would have expected under the old TEFRA payment system, where a fixed payment ceiling for all patients accompanied by a bonus payment for staying under the ceiling would clearly favor less-impaired patients. This shift in resources is also evident in the decreased LOSs for those in severe CMGs and the increased LOSs among those in the moderate CMGs.

We also tested the observation made by facility representatives that facilities achieved efficiencies by reducing the number of days spent on assessment and evaluation activities or days resulting from administrative barriers to discharge. The mean days spent in therapy declined directly with reduced

Table 7: Discharge Destination by Stroke CMG Pre- and Post-PPS

Stroke CMG	Discharge Destination	Pre-PPS (%)	Post-PPS (%)	Change (%)	P*
Mild (CMG 101–103)					.546
	Community	100.0	92.3	−7.1	
	Institution	0.0	7.1	7.1	
	Died	0.0	0.0	0.0	
Moderate (CMG 104–107)					.452
	Community	94.8	91.7	−3.1	
	Institution	5.2	8.3	3.1	
	Died	0.0	0.0	0.0	
Severe (CMG 108–114)					.948
	Community	64.0	62.0	−2.0	
	Institution	34.0	35.7	1.7	
	Died	2.0	2.3	0.3	
Total					.709
	Community	82.1	79.3	−2.8	
	Institution	17.0	19.7	2.7	
	Died	0.9	1.0	0.1	

*The chi-square test.

Table 8: OLS Regressions for Stroke Rehabilitation Utilization (n=534)

	Stroke Rehabilitation Utilization								
	LOS			Total PT and OT (min)			PT and OT (min/d)		
Independent Variables	Coeff	F	P	Coeff	F	P	Coeff	F	P
Sex (female)	−1.968	6.92	.009	−164.524	4.44	.036			
Admission motor FIM score	−0.424	192.52	<.001	−36.335	132.09	<.001			
Admission cognitive FIM score				9.929	3.33	.069	0.625	16.15	<.001
Admission CSI	0.063	4.01	.046						
Mild (CMG 101–103)							−8.554	4.24	.040
		R^2=.385			R^2=.236			R^2=.032	

Abbreviation: Coeff, coefficient.

LOS, and the number of non-PT or non-OT days did not decline as anticipated (see table 5).

Impact on Outcomes

Functional status at discharge. Table 6 provides a glimpse of the changes in functional outcomes at discharge. We found that overall, FIM scores at discharge and FIM score increase from admission to discharge declined somewhat from the pre- to post-PPS periods. However, these overall changes mask some of the changes among CMG groupings. Patients in the mild CMG grouping showed greater functional gains from the pre- to the post-PPS periods, whereas those in the moderate and severe CMG groupings showed a decline in functional gains from the pre- to post-PPS periods. A closer examination from facility to facility also showed some noticeable changes in the amount of functional gain across the 3 CMG groupings. The CMG subgroups become too small at the individual facility level to make any authoritative ohservations, except to note that observations in 1 facility tend to be cancelled out by another; thus, generalizations are difficult to make apart from these broader observations.

Discharge disposition. Overall, the percentage of patients with stroke discharged to home or to another community setting declined from 82.1% in the pre-PPS period to 79.3% in the post-PPS period, although the decline is not statistically significant. Table 7 indicates that the decline in discharge to a community setting occurred across all 3 CMG groupings. A closer facility-by-facility examination of the data uncovered no facilities that might have had a disproportionate impact on discharge disposition.

Multivariate analysis. Table 8 presents the results from the OLS regression analysis for 3 measures of stroke rehabilitation utilization—LOS, total amount of PT and OT (measured in minutes), and intensity of tberapy as measured by the minutes of therapy per day. We found that we could explain at best up to 38.5% of the variance in utilization. None of the PPS variables entered any of the 3 regression models. Table 9 presents the results for the OLS regression analysis for the change in FIM and the logistic regression analysis for discharge disposition. Again, the PPS-related variables were not major variables that explain utilization and played a secondary role in explaining the increase in FIM score.

DISCUSSION

This study provides an in-depth view of how 3 IRFs responded to the IRF-PPS in the short term. We conclude that, for these 3 facilities, the IRF-PPS did not materially reshape stroke rehabilitation case mix, utilization, and outcome in the early stages of PPS implementation, apart from the shift in therapy resources from more severely impaired patients with stroke to moderatcly impaired patients. The study's 3 IRFs reported that they made several administrative adjustments in how patients were processed to achieve greater efficiencies and reduce the numher of nontherapy days, but this observation is not borne out in the utilization and outcome data reported here. The IRFs did, of course, have to train staff to comply with the new payment system's reporting requirements. We did observe some facility-to-facility variations that pretty mucb cancelled each other out when examining the effects on the entire study group or within similar CMGs. The results of this study do not support the notion that providers would reduce services overall, although we did detect some shifts in resources among patient groups.

This study's chief advantage is that it provides detailed information about the amount of therapy services received relative to the medical and functional status of each patient with stroke during an important juncture in postacute payment

Table 9: OLS and Logistic Regressions for Stroke Rehabilitation Outcomes (n=534)

	Stroke Rehabilitation Outcomes					
	Increase in FIM			Discharge to Community		
Independent Variables	Coefficient	F	P	Estimate	Wald χ^2	P
Age	−0.314	59.68	<.001			
Race (white)	4.456	12.02	<.001			
Admission motor FIM score	−0.455	65.21	<.001	.048	13.67	<.001
Admission cognitive FIM score	−0.175	3.55	.060	.046	7.01	.008
Admission CSI	−0.222	15.08	.001			
Pre-PPS, high-TEFRA IRF	4.297	3.96	.047			
Moderate (CMG 104–107)	3.699	7.26	.007	.688*	3.54	.060
		R^2=.211			c=.794	

*Odds ratio point estimate: 1.99; 95% confidence limits, 0.97–4.08.

policy. The study's chief limitation, however, is that it examines the effects of the IRF-PPS among only 3 facilities. Although geographically diverse, we can make no claims as to the representativeness of these facilities relative to the 1200 IRFs in the United States.

CONCLUSIONS

In examining the effects of the IRF-PPS, we need to observe changes over a much longer period of time. There is a learning curve associated with every new payment and policy change, and it could be argued that the 3 IRFs represented in this study were still at the beginning stages of the learning curve. Nonetheless, providers generally are acutely aware of how payment systems affect their fiscal well-being. During the ramp-up period for the IRF-PPS, both the IRF industry and individual facilities conducted simulation analyses to determine how they would fare under the new payment system, given industry-wide and facility case mixes. Although individual facilities made numerous preparations for the implementation of the IRF-PPS, these preparations do not appear to bave materially reshaped clinical practice in the short-run apart from the shifts observed in tbis analysis.

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ORIGINAL ARTICLE

Stroke Rehabilitation Patients, Practice, and Outcomes: Is Earlier and More Aggressive Therapy Better?

Susan D. Horn, PhD, Gerben DeJong, PhD, Randall J. Smout, MS, Julie Gassaway, MS, RN, Roberta James, MStat, Brendan Conroy, MD

ABSTRACT. Horn SD, DeJong G, Smout RJ, Gassaway J, James R, Conroy B. Stroke rehabilitation patients, practice, and outcomes: is earlier and more aggressive therapy better? Arch Phys Med Rehabil 2005;86(12 Suppl 2):S101-14.

Objective: To examine associations of patient characteristics, rehabilitation therapies, neurotropic medications, nutritional support, and timing of initiation of rehabilitation with functional outcomes and discharge destination for inpatient stroke rehabilitation patients.

Design: Prospective observational cohort study.

Setting: Five U.S. inpatient rehabilitation facilities.

Participants: Poststroke rehabilitation patients (N=830; age, >18y) with moderate or severe strokes, from the Post-Stroke Rehabilitation Outcomes Project database.

Interventions: Not applicable.

Main Outcome Measures: Discharge total, motor, and cognitive FIM scores and discharge destination.

Results: Controlling for patient differences, various activities and interventions were associated with better outcomes including earlier initiation of rehabilitation, more time spent per day in higher-level rehabilitation activities such as gait, upper-extremity control, and problem solving, use of newer psychiatric medications, and enteral feeding. Several findings part with conventional practice, such as starting gait training in the first 3 hours of physical therapy, even for low-level patients, was associated with better outcomes.

Conclusions: Specific therapy activities and interventions are associated with better outcomes. Earlier rehabilitation admission, higher-level activities early in the rehabilitation process, tube feeding, and newer medications are associated with better stroke rehabilitation outcomes.

Key Words: Cerebrovascular accident; Outcome assessment; Rehabilitation; Severity of illness; Stroke.

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A MAJOR CHALLENGE in stroke rehabilitation practice is how best to customize available rehabilitation resources to meet the needs of patients to optimize outcomes.[1] Failure to optimize rehabilitation interventions and therapies can result in too little or too much care relative to a patient's needs and preferred outcomes. The association of stroke rehabilitation outcomes with process of care and patient characteristics has not been studied comprehensively. Stroke rehabilitation studies typically have been limited to a single set or subset of interventions and rarely examine all the processes of care concurrently.[2] Other studies, most of which involved limited numbers of patients, have described physical therapy (PT),[3-7] occupational therapy (OT),[8-12] and speech and language pathology (SLP)[13-16] in terms of duration or frequency but have rarely described specific activities preformed during therapy sessions.

The introductory article in this series presents the motivation, purpose, and scope of this study, as well as an extended literature review that establishes the case for the multicenter Post-Stroke Rehabilitation Outcomes Project (PSROP)[1] on which the findings presented in this article are based. Other articles in this series have documented the nature, scope, and variation of stroke rehabilitation practice as uncovered in the PSROP.[17-24]

Building on previous articles in this series that identified individual links between stroke rehabilitation patient characteristics, practices, and outcomes, this article seeks to put all of these together and describe the most significant associations between patient characteristics, PT, OT, SLP, neurotropic medications, nutritional support, and timing of initiation of rehabilitation with motor and cognitive functional outcomes and discharge destination. In short, we want to determine how specific rehabilitation therapies relate to outcomes, taking into account patient covariates.

One suggestion that emerged in previous PSROP articles is that challenging patients to perform higher-order tasks as early as possible in their rehabilitation stay, even when they may not appear ready to take on such activities, is associated with better outcomes. In other words, stroke rehabilitation patients may be able to leap-frog over lower-level activities prescribed by current traditional practice. This article further tests the hypothesis that earlier and more aggressive therapies (such as earlier rehabilitation, newer medications, enteral feeding, and higher-level therapies from physical, occupational, and speech and language therapists) are associated with better outcomes, taking into account each patient's demographic, health, and functional profile. The leap-frog hypothesis challenges conventional wisdom in rehabilitation that patients should move incrementally through the rehabilitation process and that patients should be challenged to perform activities that are only a notch above their previous level of performance in the rehabilitation process. Conventional wisdom is based, in part, on the human development axiom that one must learn to crawl before one can walk and on the notion that the patient should not be challenged excessively for fear that it may induce a sense of failure or stress, if not depression, and thus compromise outcome.

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Table 1: Patient Variables for Moderate (CMGs 104–107) and Severe (CMGs 108–114) Stroke Groups for Multiple Regression Analyses

Patient Variables	CMGs 104–107 (n=389)	CMGs 108–114 (n=441)	*P*
Demographic and health plan characteristics			
Mean age (y)	66.2	67.9	.092*
Female (%)	48.1	46.9	.781†
Race (%)			.611†
White	64.5	61.2	
Black	16.7	18.6	
Other	18.8	20.2	
Payer (%)			.102†
Medicare	57.3	63.0	
Other	42.7	37.0	
Health and functional status characteristics			
Type of stroke (%)			.068†
Hemorrhagic	22.9	28.6	
Ischemic	77.1	71.4	
Side of stroke (%)			.304†
Right	46.3	42.2	
Left	42.9	43.3	
Bilateral	9.3	11.6	
Unknown	1.5	3.0	
Location of stroke (%)			.030†
Brainstem/cerebellum	20.1	13.8	
Subcortical	30.9	39.2	
Brainstem + subcortical	6.2	4.1	
Lobar	37.3	37.4	
Unknown	5.7	5.4	
BMI/weight (%)			.115†
Underweight BMI (<18.5kg/m^2)	4.4	3.9	
Normal BMI (18.5–24.9kg/m^2)	44.5	36.7	
Overweight BMI (25–29.9kg/m^2)	33.4	37.6	
Obese BMI (≥30kg/m^2)	17.7	21.8	
Mean admission total FIM ± SD	71.6±9.9	43.1±12.6	<.001*
Mean admission motor FIM ± SD	47.8±5.7	26.6±7.2	<.001*
Mean admission cognitive FIM ± SD	23.8±7.3	16.5±7.6	<.001*
Mean admission CSI ± SD	15.8±10.4	27.3±15.2	<.001*
Stroke symptoms			
Dysphagia (%)			<.001†
Normal	54.2	21.5	
Dysphagia not otherwise specified	32.7	44.9	
Unable to swallow liquids or solids	13.1	33.6	
Motor impairment (%)			<.001†
Mild motor impairment	10.0	7.5	
Moderate motor impairment	86.1	76.0	
Severe motor impairment	3.9	16.6	
Aphasia (%)	14.9	32.9	<.001†
Neurobehavioral impairment			<.001†
Mood/behavior disturbances	38.3	33.6	
Cognitive dysfunction	4.1	8.8	
Both	8.0	16.8	
Certain neurotropic medications, no mood/behavior or cognitive dysfunction	22.9	26.5	
None	26.7	14.3	
Prerehabilitation health care			
Mean no. of days from stroke symptom onset to rehabilitation admission ± SD	11.4±12.7	18.5±29.5	<.001*

Abbreviation: SD, standard deviation.
*t test.
†Chi-square test.

The PSROP is well equipped to evaluate associations between stroke rehabilitation patients, processes, and outcomes.[17] It provides detailed, comprehensive data on stroke patient characteristics, rehabilitation treatments and interventions, and outcomes. It allows clinicians and researchers to drill down to the most meaningful level of resolution regarding the types of care rendered. Previous studies, as noted in the introductory article of this supplement, do not provide this level of resolution,[1] nor do they provide the data required to determine how various sequences of services or activities may prove more efficient and effective than

others in achieving better functional outcomes and more independent postdischarge living arrangements. This article presents promising insights that sometimes contradict conventional wisdom in stroke rehabilitation and suggest further exploration that is beyond the immediate scope of this article.

METHODS

The methodology governing the full PSROP is provided by Gassaway et al[17]; Gassaway provides a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, and a detailed description of the project's final study group. The methodology is summarized in Maulden et al.[23] The institutional review boards at Boston University and at each participating inpatient rehabilitation facility (IRF) approved the study.

Subsets of Patients With Moderate and Severe Strokes

We examined a subset (n=1079) of the total 1161 patients in the U.S. PSROP database who had FIM scores available to categorize into case-mix groups (CMGs). Because we wanted to analyze the effects of the 3 primary rehabilitation therapies (PT, OT, SLP) and 1 site provided almost no SLP information to the PSROP database, we deleted all patients from that 1 site. To maintain sample sizes large enough to detect small effects, CMGs were combined into moderate (CMGs 104−107, 389 patients) and severe (CMGs 108−114, 441 patients) patient groups. We focused regression analyses on patients with moderate and severe strokes; there were too few patients with mild stroke to be analyzed at this time (CMGs 101−103, 62 patients).

Here we briefly define the variables found to be significant in the multivariate analyses that follow.

Patient variables (table 1) include demographic characteristics, health and functional status characteristics (type and location of stroke, body mass index [BMI], admission functional status [FIM score], admission severity of illness [Comprehensive Severity Index (CSI) and its components]), indications of neurobehavioral impairments, and prerehabilitation health care information. BMI on admission was categorized as underweight ($<18.5 kg/m^2$), normal ($18.5-24.9 kg/m^2$), overweight ($25.0-29.0 kg/m^2$), and obese ($\geq 30.0 kg/m^2$). Time from stroke symptom onset to rehabilitation admission was calculated from the number of days from first symptom onset to admission to a dedicated rehabilitation unit.

CSI, a disease-specific severity assessment system, calculates severity scores using individual components of physical findings and laboratory results at specified levels of abnormality found in a resident's chart based on diseases defined by *International Classification of Diseases, 9th Revision* (ICD-9),[25] coding. For stroke diagnosis, CSI components include degree of alertness, ataxia, aphasia, dysarthria, dyspnea, perceptual and sensation impairment, dysphagia, hemiplegia, lesion level, time postinjury, and acute confusion. The functional performance for each study patient on admission to and discharge from inpatient rehabilitation was obtained via retrospective chart review using the study site's reporting of the FIM. We assumed all clinicians providing FIM data within IRFs as part of standard practice were FIM credentialed.[17]

A patient was defined as having neurobehavioral impairments if any of the following were present: (1) the patient had diagnoses associated with neurologic or behavioral impairment(s) documented in their chart (eg, major depression, ICD-9 codes 296.2 and 296.3); (2) mood or behavioral impairments were indicated in charted descriptors such as combative, agitated, restless, aggressive, anxious, depressed, emotionally labile, having hallucinations, flat affect, or impulsive; (3) cognitive impairments were indicated in charted descriptors such as decreased safety awareness, impaired or poor judgment or concentration, impaired memory, confused, disoriented, or lethargic; and (4) patients received certain neurotropic medication(s) but had no charted descriptions of mood/behavior or cognitive impairments.[21] These neurotropic medications included antidepressants, benzodiazepines, anxiolytics, and antipsychotics. Process variables (table 2) included rehabilitation length of stay (LOS); details of PT, OT, and SLP activities derived from point-of-care intervention documentation forms; and use of specific treatments, including nutrition supplementation via tube feeding and neurotropic medications, obtained from postdischarge chart review.[17-23]

The study's physicians, nurses, psychologists, social workers, and physical, occupational, recreational, and speech therapists each completed point-of-care intervention documentation forms for each patient treatment session. We calculated the total number of minutes per patient per day spent in each therapy (PT, OT, SLP) and in each therapy activity by dividing the total (full stay) number of minutes in each therapy activity by the LOS.[18-20]

Tube-feeding data included date, type, and reason a tube was placed and start and stop times of enteral formulas.[22] Based on these data, we divided patients into 3 tube-feeding groups: (1) no tube feeding during rehabilitation (n=666), (2) tube feeding at any time during rehabilitation but discontinued before discharge (n=131), and (3) tube feeding for 100% of rehabilitation stay and discharged on tube feeding support (n=33). "Discharged on tube feeding support" was defined as (1) the patient's last ordered diet type was nothing by mouth (no oral intake) or a speech and language pathologist was supervising all oral intake, (2) the CSI discharge severity indicator of the patient's dysphagia status 24 hours before discharge indicated that the patient was unable to swallow liquids or solids, (3) a percutaneous endoscopic gastrostomy or other gastrostomy tube was in place, and (4) the patient was discharged to a skilled nursing facility (SNF) or home health. Group 3 patients—patients who received tube feeding for their entire rehabilitation stay and were discharged with tube feeding (n=33)—were excluded from regression analyses. They were sicker patients overall (higher CSI scores) but had similar motor and cognitive abilities on admission as other tube-fed patients. However, they had significantly lower abilities at the time of discharge, showing lack of progress during rehabilitation, which is supported by their short LOSs and discharge to institutional care.[22] The project team determined they were an outlier group for whom the severity of dysphasia and subsequent recovery time frame were well outside usual recovery patterns.

Neurotropic medication information was collected at the drug level (including details about dosing and timing) and then grouped into categories by consensus of prescribing physicians of the PSROP clinical team based on similarity of drug content and effects on patients. Medications contained in drug categories used in these analyses, structured around medication groupings found in ePocrates,[26] are listed elsewhere.[21]

Outcome variables (table 3) included discharge function, severity of illness, and discharge destination. Function, as measured by the FIM, was captured as recorded at discharge, and change in FIM score (total, motor, cognitive) from admission to discharge was calculated. We captured the maximum CSI score and calculated increases in severity during rehabilitation from admission CSI to maximum CSI scores, which includes the most aberrant signs and symptoms regardless of when they occur.

Table 2: Process Variables for Moderate (CMGs 104–107) and Severe (CMGs 108–114) Stroke Groups for Multiple Regression Analyses

Process Variables	CMGs 104–107 (n=389)	CMGs 108–114 (n=441)	P
Mean LOS	15.7±7.2	24.5±10.9	<.001*
PT (mean ± SD)			
No. of min/d	43.5±13.6	41.4±13.9	.033*
Activities (no. of min/d)			
Bed mobility	0.7±1.0	2.5±2.3	<.001*
Sitting	0.6±1.3	2.6±3.6	<.001*
Transfers	3.2±3.1	6.1±3.9	<.001*
Sit-to-stand	2.0±2.3	3.6±2.7	<.001*
Wheelchair mobility	0.5±0.9	1.5±1.4	<.001*
Pregait	3.1±3.1	3.3±3.0	.421*
Gait	16.5±7.9	10.4±7.5	<.001*
Advanced gait	2.9±3.5	1.0±1.7	<.001*
Community mobility	1.2±2.5	0.5±1.5	<.001*
OT (mean ± SD)			
No. of min/d	40.9±15.3	39.1±15.6	.080*
Activities (no. of min/d)			
Bathing	2.1±2.5	2.1±2.3	.430*
Dressing	5.5±4.7	7.1±5.3	<.001*
Grooming	1.6±1.8	2.7±2.6	<.001*
Toileting	1.2±1.7	1.5±1.9	.025*
Feeding/eating	0.8±2.7	1.4±3.4	.001*
Transfers	2.0±2.0	2.3±2.7	.044*
Bed mobility	0.1±0.4	0.4±0.8	<.001*
Functional mobility	3.5±3.8	1.6±2.0	<.001*
Home management	3.9±4.8	1.3±2.1	<.001*
Community integration	2.0±3.2	0.8±1.9	<.001*
Leisure performance	0.8±1.5	0.7±1.3	.580*
Upper-extremity control	9.3±8.4	9.3±6.6	.989*
Wheelchair management	0.3±0.7	0.5±1.1	.001*
Sitting balance/trunk control	0.6±1.2	1.5±2.1	<.001*
SLP (mean ± SD)			
No. of min/d	25.6±16.2	31.5±15.2	<.001*
Activities (no. of min/d)			
Swallowing	3.4±6.5	6.7±8.3	<.001*
Speech/intelligibility	2.1±4.2	2.3±4.0	.394*
Voice	0.4±1.5	0.8±2.2	.005*
Verbal expression	2.9±4.8	4.0±5.4	.002*
Alternative/nonverbal expression	0.3±1.3	0.6±1.8	.005*
Written expression	0.9±2.1	0.8±1.7	.408*
Auditory comprehension	1.6±2.8	3.1±4.1	<.001*
Reading comprehension	1.4±2.3	1.4±2.2	.890*
Problem solving/reasoning	3.8±5.6	3.3±4.5	.154*
Orientation	0.6±1.5	1.1±2.0	<.001*
Attention	0.9±2.2	1.7±2.9	<.001*
Memory	1.4±3.0	1.4±2.5	.743*
Pragmatics	0.1±0.5	0.1±0.5	.551*
Executive functional skills	0.7±1.5	0.4±1.2	.001*
Tube feeding use during rehabilitation (%)			<.001†
Use discontinued before discharge	5.4	24.9	
Use continued on discharge	1.3	6.4	
None	93.3	68.7	
Neurotropic medications (%)			
Old anticonvulsant	2.8	3.0	1.000†
Opioid analgesics	18.6	29.5	<.001†
Analgesic; muscle relaxant	5.4	9.5	.026†
New SSRIs	7.5	14.3	.002†
Old SSRIs	18.0	21.8	.192†
Atypical antipsychotics	4.6	12.9	<.001†
Anti-Parkinson's	6.4	12.5	.003†
Anxiolytics	1.0	3.0	.083†
Modafinil	0.5	8.6	<.001†
Neurostimulants	3.3	13.2	<.001†

Table 2 (Cont'd): Process Variables for Moderate (CMGs 104–107) and Severe (CMGs 108–114) Stroke Groups for Multiple Regression Analyses

Variables	CMGs 104–107 (n = 389)	CMGs 108–114 (n = 441)	P
Old antinausea/antivomiting	10.3	17.7	.003†
Other antidepressants	18.0	35.4	<.001*
Benzodiazepines	11.3	13.2	.459†

Abbreviation: SSRIs, selective serotonin reuptake inhibitors.
*t test.
†Chi-square test.

Analysis Methods

Descriptive statistics were used to compare patient characteristics, therapy interventions, and outcomes for patients with moderate and severe strokes (see tables 1–3). Chi-square tests were used for categoric data and *t* tests or analysis of variance for continuous data.

We used ordinary least squares (OLS) multiple regression to examine associations between "onset days" (days from symptom onset to rehabilitation admission), medications used, nutritional support, and minutes of PT, OT, and SLP activity per patient per day with each patient's functional outcome at discharge, controlling for patient characteristics, stroke symptoms, neurobehavioral impairment, and rehabilitation LOS. We used logistic regression analyses to determine associations of the same patient characteristics and treatments with the outcomes of discharge destination to home or community or achieving specified increases in FIM components.

Variables entering regression models were checked for multicollinearity; no correlations were greater than .60. Stepwise R^2 selection procedure for OLS regressions allowed independent variables to enter and leave each model. The importance of each predictor was determined by its F value (or Wald chi square in logistic regression). We created the most parsimonious model for each outcome by allowing only significant ($P<.05$) variables to remain in the model. Variables that were allowed to enter models are listed in appendix 1. All analyses were performed with SAS statistical software.[a]

Analyses were performed within moderate and severe (CMG) stroke subpopulations. For analyses involving FIM outcomes, we excluded patients who were discharged to acute care or to another rehabilitation facility (7 patients with moderate and 37 with severe stroke) because we did not have access to FIM data scored by other facilities on discharge to home or SNF. Missing continuous data resulted in exclusion of those subjects from analyses.

For both the moderate and severe stroke CMG groupings, we performed separate regression analyses that included (1) variables based on therapy activities during the entire rehabilitation stay (tables 4, 5) and (2) variables based on therapy activities during the first block of therapy only (tables 6–8). First block of therapy is defined as receiving PT, OT, and SLP for at least 3 hours each (4h for OT) and includes activity time during only the first 3-hour (4h for OT) block. Thus, sample sizes are smaller in the first block of therapy only (see tables 6–8), because some rehabilitation patients received therapy for less than the defined first block period. Reasons for defining these blocks of time are presented elsewhere.[18-20]

For first block analyses we included only time in each activity (excluding time spent in assessment) during the first block of PT, OT, and SLP treatment time, regardless of the total number of therapy blocks a patient received during the entire rehabilitation stay. This ensured that patients were functioning at the identified FIM locomotion, transfer, and communication levels (as measured by admission FIM score), among others, at the time of receiving the therapy activities. Because we did not measure incremental increases in FIM scores during the rehabilitation stay, it was important to reduce the confounding effect of naturally improving function (natural recovery) over the course of rehabilitation. Associating outcomes at discharge with time in activities throughout the whole stay might be confounded by the natural recovery process. By using the first block of therapy, we hypothesized that patients would not

Table 3: Outcome Variables for Moderate (CMGs 104–107) and Severe (CMGs 108–114) Stroke Groups for Multiple Regression Analyses

Outcome Variables	CMGs 104–107 (n = 389)	CMGs 108–114 (n = 441)	P
Severity (CSI) during rehabilitation			
Mean maximum CSI ± SD	23.0±14.7	41.4±23.3	<.001*
Increase in severity (maximum − admission)	7.2±8.3	14.1±13.3	<.001*
Mean discharge CSI ± SD	6.4±7.1	14.8±14.1	<.001*
FIM			
Mean discharge total FIM ± SD	97.7±12.8	72.3±21.7	<.001*
Mean increase in total FIM ± SD (discharge − admission)	26.2±10.8	29.1±16.9	.003*
Mean discharge motor FIM	69.9±10.0	50.4±16.8	<.001*
Mean increase in motor FIM ± SD (discharge − admission)	22.2±9.2	23.8±14.3	.051*
Mean discharge cognitive FIM ± SD	27.7±6.1	21.8±7.6	<.001*
Mean increase in cognitive FIM ± SD (discharge − admission)	4.0±3.6	5.2±4.5	<.001*
Discharge destination (%)			<.001†
Home/community	93.3	67.1	
SNF	4.9	24.5	
Hospital or other rehab	1.8	8.4	

*t test.
†Chi-square test.

Table 4: Full Regressions for Moderate Stroke Patients CMGs 104–107

Independent Variables	Discharge FIM (R^2=.604, n=372)*†			Discharge Motor FIM (R^2=.511, n=373)*			Discharge Cognitive FIM (R^2=.793, n=376)†		
	Coeff	F	P	Coeff	F	P	Coeff	F	P
Patient variables									
Age	−0.109	15.01	<.001	−0.073	9.04	.003			
Female				−1.641	5.00	.026			
BMI underweight	−4.795	4.42	.036						
Stroke location: brainstem/cerebellum				−2.382	7.03	.008			
Admission FIM motor score	0.411	24.10	<.001	0.403	31.39	<.001			
Admission FIM cognitive score	0.666	86.25	<.001				0.668	732.56	<.001
Aphasia							−1.147	6.01	.015
Moderate motor impairment				−3.000	6.96	.009			
No. of days from stroke symptom onset to rehabilitation admission	−0.135	16.68	<.001	−0.090	9.97	.002			
Process variables									
LOS	−0.153	5.65	.018	−0.231	15.59	<.001			
PT: formal assessment (min per patient per d)				−0.374	10.41	.002			
PT: bed mobility (min per patient per d)	−1.503	8.14	.005	−1.300	8.75	.003			
PT: sitting (min per patient per d)	−0.781	4.98	.026						
PT: transfers (min per patient per d)	−0.373	5.26	.022	−0.395	7.78	.006			
PT: gait (min per patient per d)				0.129	6.48	.011			
PT: advanced gait (min per patient per d)				0.247	4.86	.028			
OT: feeding/eating (min per patient per d)							−0.139	6.50	.011
OT: bathing (min per patient per d)	0.595	9.41	.002						
OT: toileting (min per patient per d)	−1.356	22.99	<.001	−0.803	12.26	.001			
OT: sitting balance (min per patient per d)	−0.971	7.76	.006						
OT: transfers (min per patient per d)				−0.426	4.67	.031			
OT: home management (min per patient per d)	0.249	7.25	.007	0.261	10.16	.002			
OT: upper-extremity control (min per patient per d)	0.189	12.16	<.001	0.130	7.32	.007			
SLP: speech/intelligibility (min per patient per d)	−0.223	5.14	.024	−0.193	5.16	.024			
SLP: voice (min per patient per d)	1.064	12.76	<.001	0.627	6.54	.011			
SLP: auditory comprehension (min per patient per d)	−0.570	11.14	<.001	−0.397	8.73	.003	−0.162	7.59	.006
SLP: reading comprehension (min per patient per d)				0.341	4.22	.041			
SLP: problem solving (min per patient per d)	0.208	7.00	.009	0.137	4.41	.037	0.054	4.18	.042
SLP: attention (min per patient per d)	0.529	6.44	.012						
SLP: executive functioning (min per patient per d)	−0.696	5.92	.016						
Medications									
Opioid analgesics	3.140	8.68	.003	2.227	5.73	.017	0.725	3.90	.049
Atypical antipsychotics	6.127	9.28	.003	4.625	7.29	.007			
New SSRIs							1.260	4.96	.027
Anti-Parkinson's	−7.641	19.65	<.001	−4.577	9.60	.002	−1.894	9.91	.002

NOTE. Blank cells refer to variables and the coefficient, F, and P values that did not enter the model significantly.
Abbreviation: Coeff, coefficient.
*Missing 4 discharge motor FIM scores.
†Missing 1 discharge cognitive FIM scores.

have time to improve their functioning naturally as they might have if we included all therapy blocks in regression analyses.

RESULTS

Patient, Process, and Outcomes Characteristics

Patient, process, and outcome characteristics for the 830 patients with moderate and severe stroke are presented in tables 1 through 3, respectively. Demographically, the samples are similar, although the severe stroke group is slightly older. As expected, the severe stroke group differed significantly in many other patient characteristics (see table 1). They had significantly higher admission severity scores (CSI), and individual component scores of the CSI (dysphagia, complete hemiplegia or worse, aphasia, mood and cognitive disturbances) also were more severe. By definition, the severe stroke group also had significantly lower admission FIM scores (total, motor, cognitive). In addition, the severe stroke group had more time between onset of stroke symptoms and rehabilitation admission.

Many process variables also were significantly different between the moderate and severe stroke groups (see table 2). Rehabilitation LOS was significantly longer for the severe stroke group. Time spent in therapy activities varied among the 2 groups, often significantly. Significantly more time was spent on higher-level PT (gait, advanced gait, community mobility), OT (home management and community integration), and SLP activities (executive function skills) in the moderate stroke group. Tube feeding was used significantly more with patients with severe stroke. Medications administered to the 2 groups also were different for several classes of neurotropic medications: there was greater use of opioid analgesics, analgesic

Table 5: Full Regressions for Severe Stroke Patients CMGs 108–114

Independent Variables	Discharge FIM (R^2=.728, n=372)*			Discharge Motor FIM (R^2=.676, n=372)*			Discharge Cognitive FIM (R^2=.796, n=376)			Discharge Home and Assisted Living (c=.836, n=413)		
	Coeff	F	P	Coeff	F	P	Coeff	F	P	Coeff	Wald	P
Patient variables												
Age	−0.219	25.80	<.001	−0.202	31.94	<.001						
Race: black	−3.253	4.74	.030	−2.981	5.58	.019						
Admission FIM motor score	0.430	12.96	<.001	0.378	15.48	<.001				0.075	10.39	.001
Admission FIM cognitive score	0.880	81.82	<.001	0.297	14.99	<.001	0.575	345.80	<.001			
Aphasia							−1.429	8.48	.004			
Mild motor impairment	6.041	7.24	.008	5.010	7.14	.008						
Neurobehavioral impairment: mood and cognitive disturbances (both)	−4.185	6.64	.010				−2.389	24.54	<.001			
No. of days from stroke symptom onset to rehabilitation admission	−0.085	18.01	<.001	−0.080	22.81	<.001						
Process variables												
LOS	0.180	7.38	.007				0.091	30.42	<.001	0.037	7.29	.007
PT: formal assessment (min per patient per d)	−0.880	8.97	.003	−0.948	17.01	<.001				−0.210	7.41	.007
PT: bed mobility (min per patient per d)	−1.547	22.80	<.001	−1.469	33.71	<.001						
PT: transfers (min per patient per d)										0.167	16.42	<.001
PT: gait (min per patient per d)	0.527	31.19	<.001	0.497	39.60	<.001				0.065	8.12	.004
PT: advanced gait (min per patient per d)	2.010	29.02	<.001	1.845	35.87	<.001	0.427	16.8	<.001	0.364	9.57	.002
OT: dressing (min per patient per d)										−0.094	11.39	<.001
OT: grooming (min per patient per d)	−0.701	6.37	.012				−0.225	8.09	.005			
OT: bed mobility (min per patient per d)							−0.567	4.85	.028			
OT: functional mobility (min per patient per d)							0.234	7.17	.008			
OT: community integration (min per patient per d)							0.310	11.73	<.001			
OT: home management (min per patient per d)	1.189	17.30	<.001	0.998	17.20	<.001				0.372	10.77	.001
OT: wheelchair (min per patient per d)										−0.361	8.05	.005
SLP: swallowing (min per patient per d)				−0.179	6.76	.010						
SLP: verbal expression (min per patient per d)							0.129	7.79	.006			
SLP: auditory comprehension (min per patient per d)							−0.282	19.99	<.001			
SLP: reading comprehension (min per patient per d)				0.470	4.59	.033						
SLP: problem solving (min per patient per d)	0.437	10.76	.001				0.192	22.06	<.001			
SLP: orientation (min per patient per d)	−0.985	9.03	.003	−0.692	6.49	.011	−0.457	21.69	<.001			
SLP: attention (min per patient per d)										−0.102	5.60	.018
Tube feeding during rehabilitation	3.651	5.60	.019	4.172	9.80	.002						
Medications												
Old SSRIs	−3.867	7.50	.007	−3.447	8.35	.004						
Modafinil	−10.70	16.77	<.001	−8.730	16.32	<.001						
Anti-Parkinson's	−6.388	12.40	<.001	−4.908	10.44	.001						

NOTE. Blank cells refer to variables and their coefficient, F, and *P* values that did not enter the model significantly.
*Missing 4 discharge motor FIM scores.

Table 6: Full Regressions for Moderate Stroke Patients CMGs 104–107, First Therapy Block Only

Independent Variables	Discharge FIM (R^2=.546, n=283)*			Discharge Motor FIM (R^2=.480, n=283)*			Discharge Cognitive FIM (R^2=.772, n=287)		
	Coeff	F	P	Coeff	F	P	Coeff	F	P
Patient variables									
Age	−0.154	19.81	<.001	−0.143	23.95	<.001	−0.024	4.69	.031
Stroke location: brainstem/cerebellum				−2.943	7.73	.006			
Stroke location: subcortical	2.318	4.40	.037						
Admission FIM motor score	0.481	23.95	<.001	0.457	30.55	<.001			
Admission FIM cognitive score	0.613	52.83	<.001				0.688	619.09	<.001
Aphasia							−1.181	5.52	.020
Moderate motor impairment	−4.853	9.69	.002	−5.598	18.09	<.001			
No. of days from stroke symptom onset to rehabilitation admission	−0.094	6.09	.014	−0.078	5.72	.018			
Process variables									
LOS	−0.205	7.57	.006	−0.189	8.74	.003			
PT: sitting (min in first 3h of therapy)				−0.161	5.34	.022			
PT: transfers (min in first 3h of therapy)				−0.095	8.30	.004			
PT: gait (min in first 3h of therapy)	0.059	10.23	.002	0.046	8.15	.005			
OT: bathing (min in first 4h of therapy)				−0.060	5.27	.022			
OT: feeding/eating (min in first 4h of therapy)	−0.060	6.10	.014	−0.050	6.12	.014			
OT: toileting (min in first 4h of therapy)							0.038	5.75	.017
SLP: voice (min in first 3h of therapy)	0.093	4.79	.030	0.115	10.16	.002			
SLP: auditory comprehension (min in first 3h of therapy)	−0.162	19.64	<.001	−0.091	9.60	.002	−0.028	5.27	.023
Medications									
Old anticonvulsants	6.655	4.67	.032	5.173	3.87	.050			
Analgesics; muscle relaxant	−7.560	11.39	<.001	−7.446	15.00	<.001			
Opioid analgesics	2.972	5.27	.022	2.388	4.65	.032			
Neurostimulants	−7.076	6.32	.013						
Anti-Parkinson's	−4.962	5.61	.019				−2.320	11.17	.001
Old antinausea/antivomiting							1.180	3.97	.047

NOTE. Blank cells refer to variables and their coefficient, F, and P values that did not enter the model significantly.
*Missing 4 discharge motor FIM scores.

muscle relaxants, new selective serotonin reuptake inhibitors (SSRIs), atypical antipsychotics, anti-Parkinson's medications, modafinil, neurostimulants, other antidepressants, and old antinausea and antivomiting medications in patients with severe stroke.

Outcome measures also varied significantly for patients with moderate and severe stroke. Discharge total, motor, and cognitive FIM scores were higher for patients with moderate stroke. However, patients with severe stroke achieved greater increases in total, motor, and cognitive FIM scores from admission to discharge. Discharge and maximum CSI scores were significantly higher (indicating sicker patients) for patients with severe stroke; patients with severe stroke also had a greater increase in severity during rehabilitation. Significantly more patients with moderate stroke were discharged to home or community (see table 3).

Regression Results for All Patients With Moderate and Severe Stroke

We allowed many variables (eg, demographics; function at admission [FIM score]; medical severity of illness [maximum CSI score]; components of severity; stroke location; minutes per day spent on PT, OT, and SLP activities; medication class; nutritional support; LOS) (see tables 1, 2) to enter stepwise selection regression models to identify those variables associated with higher or lower functional outcome by discharge or more or less likelihood of being discharged to home or community versus institution (SNF, hospital, other rehabilitation center).

Tables 4 and 6 present 2 regression approaches for patients with moderate CMG (104−107) stroke, and tables 5 and 7 present 2 regression approaches for patients with severe CMG (108−114) stroke. The first approach for each group contained information and interventions from the full rehabilitation stay (see table 4); the second approach (see table 6) used the amount of PT, OT, and SLP from the first block of therapy only. Outcomes included discharge total, motor, and cognitive FIM scores. In addition, for the severe stroke group (CMG 108−114) we included discharge destination as a fourth outcome. Discharge destination was not used as an outcome for patients with moderate stroke because almost all of these patients went home (see table 3).

Demographic Variables

In each model, older patients were associated with lower discharge FIM scores for at least 2 specified outcomes. Race (ie, black) was associated with lower discharge total and motor FIM scores for patients with severe stroke.

Health and Functional Status Variables

Stroke location. Patients in the moderate group with brainstem and cerebellar strokes were associated with lower discharge motor FIM scores.

Table 7: Full Regressions for Severe Stroke Patients CMGs 108–114, First Therapy Block Only

Independent Variables	Discharge FIM (R^2 .559, n=331)*			Discharge Motor FIM (R^2 .479, n 331)*			Discharge Cognitive FIM (R^2=.742, n=335)			Discharge Home and Assisted Living (c .745, n 365)		
	Coeff	F	P	Coeff	F	P	Coeff	F	P	Coeff	Wald	P
Patient variables												
Age	−0.330	30.98	<.001	−0.324	43.14	<.001						
Race: other							−1.153	5.33	.022			
Stroke side: right brain							1.289	9.39	.002			
Admission FIM motor score	0.635	17.78	<.001	0.656	27.53	<.001				0.113	31.66	<.001
Admission FIM cognitive score	0.959	63.71	<.001	0.216	4.65	.032	0.666	362.28	<.001			
Maximum severity score (CSI)	−0.081	3.92	.048				−0.031	8.83	.003			
Aphasia							−1.063	4.23	.041			
Severe motor impairment	−7.871	11.53	<.001	−6.094	9.73	.002	−1.482	6.08	.014			
No dysphagia				3.405	4.53	.034						
Neurobehavioral impairment: mood and cognitive disturbances (both)	−4.846	5.20	.023				−1.964	11.11	.001	−0.671	4.12	.042
Neurobehavioral impairment: neurotropic medications, no mood/ behavior or cognitive dysfunction				3.364	5.04	.026						
No. of days from stroke symptom onset to rehabilitation admission	−0.119	21.47	<.001	−0.114	27.62	<.001	−0.014	4.07	.045			
Process variables												
LOS	0.395	22.26	<.001	0.246	12.78	<.001	0.127	36.58	<.001	0.068	25.50	<.001
PT: bed mobility (min in first 3h of therapy)	−0.170	6.54	.011	−0.168	9.03	.003						
PT: gait (min in first 3h of therapy)	0.121	13.06	<.001	0.106	13.95	<.001						
PT: advanced gait (min in first 3h of therapy)	0.337	4.81	.029	0.268	4.27	.040	0.126	9.01	.003			
OT: bed mobility (min in first 4h of therapy)							−0.070	4.37	.037			
OT: home management (min in first 4h of therapy)	0.176	6.57	.011	0.159	7.48	.007						
SLP: problem solving (min in first 3h of therapy)							0.023	5.16	.024			
SLP: orientation (min in first 3h of therapy)							−0.041	4.87	.028			
Tube feeding during rehabilitation	4.850	6.19	.013	4.700	7.93	.005						
Medications												
Old SSRIs	−5.346	8.27	.004	−4.616	8.73	.003						
Other antidepressant	−3.663	4.95	.027	−4.206	9.03	.003				−0.593	5.22	.022

NOTE. Blank cells refer to variables and their coefficient, F, and P values that did not enter the model significantly.
*Missing 4 discharge motor FIM scores.

Admission FIM score. Patients with higher admission motor and cognitive FIM scores were associated with higher discharge FIM scores and with more likelihood of being discharged home.

Severity of illness. Maximum severity scores were associated with lower discharge total and cognitive FIM scores in the first block analyses of patients with severe stroke. The high correlation of maximum severity score and admission FIM score in patients with severe stroke ($r = -.491$, $P<.001$) partially explains the CSI's overall lack of significance in regression models that include the entire rehabilitation stay. However, components of the CSI including aphasia, levels of motor impairment, neurobehavioral impairment, and dysphagia entered each model as indicated. Patients with an aphasia diagnosis were associated with lower discharge cognitive FIM scores during rehabilitation (all models).

When the CSI and its related components were not allowed to enter models by not including them in the variable selection list, the R^2 and c statistics changed little (between 0% and 4.3%). Also, none or very few other predictors changed. Hence, the models were stable. This indicates that it is important to control for the CSI and its components but that other detailed process predictor variables correlate sufficiently with the CSI to retain the overall explanatory power of the models. When detailed process data were not available, the CSI explained between 12% and 20% of additional variation in outcomes beyond patient demographic data.[17]

Time of onset of symptoms to rehabilitation admission. In all models, more time from onset of stroke symptoms to rehabilitation admission was associated with lower discharge total and motor FIM scores.

Process Variables

Length of stay. Longer rehabilitation LOS was associated significantly with lower discharge total and motor FIM scores for patients with moderate stroke. In contrast, however, for patients with severe stroke, longer LOS as associated signifi-

Table 8: Significant Therapy Variables Predicting Discharge FIM Walk and Toilet Transfer Levels, First Therapy Block Only

Independent Variables	3 to 18 Hours of PT			3 to 24 Hours of PT*			3 to 77 Hours of PT†		
	Coeff	Wald	P	Coeff	Wald	P	Coeff	Wald	P
Walking patients starting at admission FIM locomotion/walk level 1 and ending at level 4 or higher	n=119, c=.864			n=151, c=.836			n=177, c=.786		
PT: gait (min in first 3h of therapy)	0.047	15.29	<.001	0.042	16.52	<.001	0.040	18.77	<.001
PT: transfers (min in first 3h of therapy)	−0.061	9.51	.002	−0.027	3.76	.052			
PT: community mobility (min in first 3h of therapy)	−0.255	5.63	.018	−0.232	5.02	.025			
OT: home management (min in first 4h of therapy)	0.072	4.81	.028						
Admission FIM motor score							0.079	7.52	.006
Dysphagia not otherwise specified				−0.914	4.96	.026			
Neurobehavioral impairment: cognitive disturbances	2.481	6.25	.012						
Neurobehavioral impairment: mood disturbances				−1.051	6.09	.014			
LOS	0.093	6.04	.014	0.084	9.10	.003	0.066	11.46	<.001
No. of days from stroke symptom onset to rehabilitation admission							−0.017	4.34	.037
Patients starting at admission FIM toilet transfer level 1 and ending at level 4 or higher	n=113, c=.863			n=136, c=.857			n=163, c=.837		
PT: gait (min in first 3h of therapy)	0.033	8.63	.003	0.037	11.72	<.001	0.039	13.34	<.001
OT: feeding/eating (min in first 4h of therapy)	−0.042	5.63	.018	−0.035	5.60	.018	−0.034	6.08	.014
SLP: reading comprehension (min in first 3h of therapy)	0.078	5.70	.017	0.064	5.11	.024	0.078	8.38	.004
Admission FIM motor score	0.126	8.44	.004	0.091	4.73	.030	0.113	9.87	.002
Maximum severity score (CSI)				−0.026	4.34	.037			
LOS				0.071	5.83	.016	0.037	4.76	.029
Sedating antihistamine medication	−2.760	4.27	.039						
New antinausea/antivomiting medication							−1.641	5.07	.024

NOTE. Patients in severe stroke CMGs 108–114. Blank cells are not significant.
*Includes first (3–18h) column.
†Includes first 2 (3–18h and 3–24h) columns.

cantly with higher discharge total and cognitive FIM scores and greater likelihood of being discharged to home.

Therapy. A variety of PT, OT, and SLP activities were associated significantly with higher or lower discharge FIM scores and discharge destination. Consistently, more minutes per day spent in PT gait activities, OT upper-extremity control and home management activities, and SLP problem-solving activities were associated significantly with higher discharge FIM scores and greater rates of discharge to home. Other therapy activities were associated consistently with lower discharge FIM scores: more minntes per day spent in PT bed mobility and sitting, OT bed mobility, and SLP auditory comprehension and orientation.

Medications. Use of anti-Parkinson medications (bromocriptine, pergolide, pramipexole, carbidopa/levodopa, amantadine) was associated significantly with lower discharge FIM scores. Interestingly, only 5 (0.6%) patients had a diagnosis of Parkinson's disease. Use of new SSRI medications (citalopram, escitalopram), opioid analgesics (codeine, fentanyl, hydrocodone, hydromorphone, methadone, morphine, oxycodone, propoxyphene), and atypical antipsychotics (clozapine, olanzapine, quetiapine, risperidone) were associated with higher discharge FIM scores; however, use of older SSRI medications (fluoxetine, paroxetine, sertraline) had a significant association with lower discharge FIM scores.

Tube feeding. Enteral tube feeding was associated significantly with higher discharge total and motor FIM scores for patients with severe stroke, even when controlling for degree of dysphagia and other variables. It was not a significant variable in regression models for patients with moderate stroke.

Regression Results for Patients Admitted at FIM Locomotion Level 1 or Toilet Transfer Level 1

It could be argued that, in tables 4 through 7, discharge FIM scores do not isolate adequately the effects of individual therapies to specific areas of function because we look at the impact of individual therapy activities on broad categories of function such as total FIM and motor FIM scores. In table 8, we take a more focused approach. We looked at patients in the severe stroke gronp who started at FIM locomotion/walk level 1 (n=177) and tried to determine which therapies in the early stages (first block only) made a difference in getting patients from locomotion/walk level 1 to a locomotion/walk level of 4 or higher. We also wanted to consider how important the first block of therapy was regardless of how many additional blocks of therapy a patient received in total. Here, we found that minutes of gait training in the first block of therapy was consistently the most important PT activity associated with better outcome, regardless of the total amount of PT rendered over the course of the rehabilitation stay, while controlling for other patient characteristics.

We also wanted to determine whether benefits of gait training generalized to other lower-level functional areas that one might focus on before gait training. In this case, we arbitrarily chose toilet transfer and considered those patients who started at toilet transfer level 1 and progressed to level 4 or higher (see table 8). Again, we found that amount of time spent on gait in the first block was the most important predictor in advancing from FIM toilet transfer level 1 to level 4 or higher, while controlling for

other patient covariates. Early gait training appears to allow the patient to leap-frog over lower levels of toilet transfer.

DISCUSSION

Many of the results in tables 4 through 8 are in the expected direction and are consistent with findings in other studies that have examined the relation between patient characteristics, functional status, LOS, and outcome. What is different here is the ability to examine how specific therapy activities, medications, and other interventions are associated with outcomes. There are 2 consistent findings across all regressions presented in this article. The first is that earlier is associated with better. We found a strong and consistent negative association between time of stroke symptom onset to rehabilitation admission and functional outcomes. In other words, the sooner a patient with stroke starts inpatient rehabilitation after his/her stroke, no matter how severe, the better the outcome. Moreover, we find that earlier gait activities, particularly in the first block of PT, have a significant association with outcome, regardless of how much additional therapy a patient receives or what his/her admission functioning level (FIM score) is. This second finding supports more aggressive therapy. That is, earlier participation in higher-order, more challenging therapy activities, even at the outset in the first block of therapy and even for low-functioning patients, is associated with better outcomes in general, and extended participation in lower-level activities often is associated with worse outcomes. Participation in higher-order or more difficult therapeutic activities appears to assist in the improvement of lower-level functional activities, even without direct attention to that activity. This last observation was most evident in examining how gait training during the first block of therapy was associated strongly with greater independence in toilet transfers (see table 8). Also, Hatfield et al[20] found that it may not be necessary to spend much time enhancing basic verbal expression skills. Instead, therapists should initiate problem-solving activities, and the verbal expression will come back in the process.

These findings challenge conventional wisdom in rehabilitation practice. It is important to understand the nature of this conventional wisdom and how it arises. Rehabilitation clinicians work with patients in particular ways based on how they were taught or based on therapeutic theories and approaches espoused by textbook authors. Although often unsupported by scientific evidence, the theories and approaches make a good deal of intuitive sense and become incorporated into conventional wisdom and practice.

A few examples may be helpful here. Consider Rood's clinical maxim: "Proximal stability before distal mobility." It suggests that a patient cannot learn to use their hands or feet if their trunk and proximal limbs are weak. Consider a clinical rule of thumb in rehabilitation: activities should be planned to allow a patient to be successful for 80% of trials, thus minimizing his/her frustration and risk of depression due to excessive experience of failure. Also consider the theory underlying neurodevelopmental treatment, developed from the pioneering pediatric rehabilitation work of Bobath. It is a therapeutic approach that can be described simplistically based on the observation that a child first learns to crawl and integrate spinal and brainstem reflexes before learning to walk. Finally, consider the theory underlying the Fugl-Meyer Assessment of motor recovery after stroke. It was developed as the first quantitative evaluative instrument for measuring sensorimotor stroke recovery, based on Twitchell and Brunnstrom's observations and conceptualization of the "sequential stages of motor return" in hemiplegic patients with stroke.[27] Collectively, these theories and approaches advocate starting at a patient's current level of functioning and then building gradually toward recovery of normal function. Some of our findings challenge these time-honored theories and approaches.

Other findings actually reinforce conventional wisdom. The finding that earlier is better supports the rehabilitation axiom that patients should start rehabilitation sooner rather than later and that delaying rehabilitation can have a deleterious effect on outcomes. Rehabilitation clinicians have long been concerned that, with extended stays in acute care, patients becomes progressively deconditioned and less able to partake fully in rehabilitation on transfer to a rehabilitation unit. Again, data analyses presented here suggest that the sooner patients with stroke, especially those with severe stroke, get to the rehabilitation setting, the more likely they are to have an optimal gain in FIM score and have the best chance of being discharged to home instead of being institutionalized. This may mean transferring patients who are not yet 100% stable (eg, may have a urinary tract infection or pneumonia) to a rehabilitation unit more quickly, rather than spending a few more days in the hospital waiting for complete stabilization.

Rehabilitation providers often wonder if the acute care hospital payment system encourages acute care providers to discharge patients to rehabilitation when they are not yet medically stable. The findings here suggest that "sicker and quicker" may in some cases be better. This inference is supported by the variables that have significant association with discharge total and motor FIM scores (see tables 4 through 7). A longer time between onset of stroke symptoms and admission to inpatient rehabilitation was associated with reduced discharge FIM score, after controlling for overall severity of illness or its components. This suggests that earlier admission to rehabilitation, even if a patient's severity of illness is increased according to a higher CSI score or its components, is associated with better outcomes. In any event, the findings should encourage more timely coordination in the handoff from acute care to rehabilitation for patients with stroke and more willingness of rehabilitation facilities to admit medically challenging, sicker, patients.

Once in rehabilitation, patients appear to have different responses to LOS. For patients in the moderate stroke CMGs (104–107), our findings indicate that there is a negative association of longer LOS with outcomes. However, for patients in the severe CMGs (108–114), our findings indicate that there is a strong positive association of longer LOS with outcomes. At the risk of overinterpreting these findings, one could conclude that patients with moderate stroke do better with shorter and more intense rehabilitation stays, whereas patients with severe stroke do better with a more extended rehabilitation process. More data analyses are needed to determine accurately the relation between rehabilitation LOS and outcomes among various subgroups of rehabilitation patients to identify more clearly the rehabilitation patients who would benefit from shorter or longer rehabilitation stays.

Common clinical practice also has a powerful sway in the choice of medications. A few years ago, stroke rehabilitation physicians were happy to adopt the use of SSRI medications for patients with depressed mood because of remarkably low side effect profiles compared with tricyclic antidepressants, which were notorious for side effects. The first generation of SSRIs included fluoxetine, sertraline, and paroxetine. A newer generation of SSRIs, including citalopram and escitalopram, has been developed and adopted into use by psychiatric physicians; however, rehabilitation physicians have been slower to adopt them. Given that there are few side effects from the first generation SSRIs and little to no research on the merits or side effects of newer SSRIs on patients undergoing stroke rehabil-

itation, there is no strong reason to shift to the unknown from the well established. However, our analyses indicate that stroke rehabilitation patients might benefit from such a shift.

It is also common clinical practice to avoid the use of antipsychotic medications, based on beliefs extrapolated from animal research and psychiatric literature that the antidopaminergic and anticholinergic effects of chlorpromazine and haloperidol, among others, could reduce alertness and learning capacity in stroke survivors. A new family of medications referred to as atypical antipsychotic medications (olanzepine, quetiapine, risperidone, ziprasidone) has seen little use in stroke rehabilitation because its newness, a long-standing bias against antipsychotic medications as a group, and the lack of randomized studies in the stroke population. This persists despite the growing literature showing nootropic effects of this family of medications.[21] Our analyses indicate that patients with stroke might benefit from greater use of atypical antipsychotics. Conroy et al[21] found that new atypical antipsychotic medications and second generation SSRIs appear to have a positive association with stroke rehabilitation outcomes.

Another family of medications for which there exists a long-standing bias against use in stroke rehabilitation is narcotic pain medications. Narcotics are understood to sedate patients, dull cognition, cause depression, and reduce respiratory drive and, therefore, are expected to diminish outcomes if used in stroke rehabilitation. A lack of specific research examining medication use in stroke rehabilitation allows common clinical practice to prevail. Our data suggest otherwise—that narcotic pain medications are effective in reducing pain and that patients make greater improvements in motor FIM scores with them than without, despite their sedating and cognitive dulling effects.[21]

In summary, the PSROP database is large enough that we can locate narrow subpopulations where actual clinical activities and interventions went against common clinical practice: patients given narcotic or atypical antipsychotic medications consistently, low-functioning patients (admission FIM scores of 1 for locomotion or toilet transfer) who participated in PT sessions in their first 3 hours of PT where they practiced gait activities, and patients requiring total assistance for toileting who participated in PT where a therapist practiced gait in the first 3 hours of therapy. Results from these analyses indicate a strong and consistent association of rehabilitation activities that challenge patients and stress them well beyond their current level with better outcomes; that is, they move quickly to practicing upper-extremity functional activities rather than focusing on trunk strengthening. (The trunk will strengthen secondarily out of necessity.) There seem to be positive benefits for patients to jump ahead in the established sequence of activities and leap-frog into activities that might seem excessively challenging for them according to common clinical practice.

These findings challenge rehabilitation providers to rethink how they approach patients. They suggest that many current strategies about how to help a patient improve may not be optimal. Work carried out in the PSROP is not intended to reduce the value of rehabilitation but to discover its best aspects. Rehabilitation clinicians will continue to work on trunk stability, make sure a patient can move in bed, and choose to use fluoxetine at times. The difference may be in the timing and knowing when is the best opportunity to use each technique with specific types of patients.

The findings presented here are based on findings from facilities in the United States. The larger study also included a rehabilitation facility in New Zealand. Overall, the findings here are consistent with findings arising from our comparison of practice and outcomes between facilities in the United States and New Zealand, presented in this supplement by McNaughton et al.[28] This comparison notes that U.S. stroke rehabilitation patients received earlier and more intense rehabilitation and had better outcomes despite presenting a more severe clinical profile on admission.

Limitations

Several of the PSROP's limitations are noted in the study's baseline methods article by Gassaway et al[17] and in other articles in this supplement.[18-23] Observational studies such as this, however, naturally raise several concerns. We want to address 3 of them: (1) controlling for patient differences, (2) selection bias, and (3) association versus causation. The first 2 are closely related.

The strength of an observational study depends on the study's ability to control for patient differences that would otherwise be addressed through randomization. In the absence of randomization, it is critical that important patient covariates be addressed adequately. As noted in the study's baseline methods article,[17] the study's use of the admission FIM and the CSI scores provides a comprehensive patient functional and severity profile, although there is always the chance that some unknown critical variable may have been overlooked.

Selection bias is a concern when patients are not randomly assigned to certain treatment arms or when some patients fail to enroll in the study or drop out. In this study, there was no treatment arm, sham treatment, or placebo; the study examined only existing practice. Moreover, in this study, patients entered the study consecutively as they were admitted to the facility. There was no formal enrollment or informed consent because no new intervention was being introduced—and thus there were no dropouts that might otherwise bias the study sample.

The chief criticism of any observational study of this genre is that association is not causation. We agree. But when associations remain consistent regardless of how the study group is partitioned or when the findings are tested from other vantage points, the evidence becomes increasingly persuasive and needs to be taken seriously despite the exploratory nature of the study. One of the next steps is to determine the predictive validity of the study's findings. One way this can be done is to implement the findings as suggested here and then evaluate whether the outcomes observed are those that were predicted. The field also could conduct 1 or more randomized clinical trials to test these findings to determine more conclusively the predictive validity of the findings. A more formal trial of the study's leap-frog hypothesis would be particularly compelling.

The analyses presented here examine the relation between rehabilitation activities and interventions and outcomes on discharge from rehabilitation. These findings would be even more compelling if they were also found to be true for longer-term outcomes (eg, 6 and 12mo postonset). Funding limitations simply did not allow the research team to look beyond the patients' discharge statuses.

CONCLUSIONS

The PSROP's database allows researchers and clinicians to examine a rich array of associations between rehabilitation patients, processes, and outcomes. The database enables investigators to discover treatment practices that are associated with better outcomes for patients with stroke, taking into account their demographic and clinical profiles. A key finding is that earlier and more aggressive therapy is better. We find that starting therapy sooner after a stroke and starting higher-order or more challenging activities sooner are associated with better outcomes, even with lower-level functioning patients. We find this to be the case for each of 3 rehabilitation sentinel thera-

pies—PT (early gait activities), OT (early community mobility activities), and SLP (early problem solving activities). In the area of medication use, the analyses suggest that making the jump to newer SSRI antidepressant and atypical antipsychotic medications is associated with greater ability to benefit from inpatient rehabilitation for our patients.

These findings have significant implications for future research. Our findings suggest that health care providers need to shorten the duration from onset of stroke to onset of rehabilitation and to move patients as quickly as possible to higher-level, more difficult therapy activities and that rehabilitation providers may be able to shorten the LOS for some patients but increase the LOS for others. Validation studies may lead to changes in clinical practice and health policy as it relates to rehabilitation. These findings suggest continued study to reconsider target LOSs and payment weights associated with various CMGs in the IRF prospective payment system. They provide us the opportunity to develop more creative stroke rehabilitation "products" that could better coordinate each patient's care from stroke onset to rehabilitation and to discharge.

A strength of the clinical practice improvement (CPI) approach is the ability to uncover best practices more quickly than conventional studies. Such practices can later be vetted in validation studies or through controlled trials. A dilemma we have now is determining what therapeutic activities and interventions are truly ready for prime-time controlled studies. By focusing exclusively on randomized studies, we risk wasting valuable rehabilitation research resources on studies that may show no or minimal differences. Through use of CPI studies, therapeutic activities and interventions can be identified and unproductive activities and interventions can be weeded out before such confirmatory studies. The results here require us to validate the findings (predictive validity) through actual implementation and perhaps clinical trials and to rethink aspects of stroke rehabilitation practice and policy.

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APPENDIX 1: VARIABLES ALLOWED TO ENTER AND LEAVE REGRESSION MODELS

Independent variables allowed:

- Age
- Female
- Race – black
- Race – other
- Payer – Medicare
- BMI – underweight
- BMI – normal
- BMI – overweight or obese
- Stroke type – hemorrhagic

APPENDIX 1: VARIABLES ALLOWED TO ENTER AND LEAVE REGRESSION MODELS (cont'd)

Independent variables allowed:

- Brain side – right
- Brain side – left
- Brain side – bilateral
- Stroke location – lobar
- Stroke location – subcortical
- Stroke location – brainstem/cerebellum
- Stroke location – brainstem + subcortical
- FIM score – admission motor
- FIM score – admission cognitive
- CSI severity score – maximum
- Aphasia during rehabilitation
- Level of motor impairment – severe
- Level of motor impairment – moderate
- Level of motor impairment – minimal
- Dysphagia – unable to swallow solids or liquids
- Dysphagia not otherwise specified
- Dysphagia – none or missing
- Neurobehavioral impairment – both mood/behavior disturbances + cognitive dysfunction
- Neurobehavioral impairment – cognitive dysfunction
- Neurobehavioral impairment – mood/behavior disturbances
- Neurobehavioral impairment – neurotropic medication use, no mood/behavior or cognitive dysfunction
- Number of days from stroke onset symptoms to rehabilitation
- Rehabilitation length of stay
- PT activity formal assessment, mean number of min/d
- PT activity bed mobility, mean number of min/d
- PT activity sitting, mean number of min/d
- PT activity transfer, mean number of min/d
- PT activity sit-to-stand, mean number of min/d
- PT activity wheelchair mobility, mean number of min/d
- PT activity pregait, mean number of min/d
- PT activity gait, mean number of min/d
- PT activity advanced gait, mean number of min/d
- PT activity community mobility, mean number of min/d
- OT activity formal assessment, mean number of min/d
- OT activity bathing, mean number of min/d
- OT activity dressing, mean number of min/d
- OT activity grooming, mean number of min/d
- OT activity toileting, mean number of min/d
- OT activity feeding/eating, mean number of min/d
- OT activity transfers, mean number of min/d
- OT activity bed mobility, mean number of min/d
- OT activity functional mobility, mean number of min/d
- OT activity home management, mean number of min/d
- OT activity community integration, mean number of min/d
- OT activity leisure performance, mean number of min/d
- OT activity upper-extremity control, mean number of min/d
- OT activity wheelchair mobility, mean number of min/d
- OT activity sitting balance, mean number of min/d
- SLP activity formal assessment, mean number of min/d
- SLP activity swallowing, mean number of min/d
- SLP activity speech/intelligibility, mean number of min/d
- SLP activity voice, mean number of min/d
- SLP activity verbal expression, mean number of min/d
- SLP activity alternative/nonverbal expression, mean number of min/d
- SLP activity writing expression, mean number of min/d
- SLP activity auditory comprehension, mean number of min/d
- SLP activity reading comprehension, mean number of min/d

APPENDIX 1: VARIABLES ALLOWED TO ENTER AND LEAVE REGRESSION MODELS (cont'd)

Independent variables allowed:
SLP activity problem solving, mean number of min/d
SLP activity orientation, mean number of min/d
SLP activity attention, mean number of min/d
SLP activity memory, mean number of min/d
SLP activity pragmatics, mean number of min/d
SLP activity executive functioning, mean number of min/d
Enteral tube feeding during rehabilitation
Anticonvulsant medication, new
Anticonvulsant medication, old
Anticonvulsants medication, detrimental to cognition
Antidepressant medication, other
Antidepressant medication SSRI, new
Antidepressant medication SSRI, old
Antidepressant tricyclic medication
Analgesic; muscle relaxant medication
Opioid analgesic medication
Sedating antihistamine medication
Benzodiazepine medication
Antinausea/antivomiting medication, old
Antinausea/antivomiting medication, new
Atypical antipsychotic medication
Traditional antipsychotic medication
Modafinil medication
Neurostimulant medication
Anti-Parkinson's medication
Anxiolytic medication
Hypnotic medication

Reference categories (variables not allowed in regression models):
Brain side – unknown
Stroke location – unknown
Race – white
Neurobehavioral impairment – no mood/behavior or cognitive dysfunction or neurotropic medication use

Abbreviation: SSRIs, selective serotonin reuptake inhibitors.

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ORIGINAL ARTICLE

A Comparison of Stroke Rehabilitation Practice and Outcomes Between New Zealand and United States Facilities

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ABSTRACT. McNaughton H, DeJong G, Smout RJ, Melvin JL, Brandstater M. A comparison of stroke rehabilitation practice and outcomes between New Zealand and United States facilities. Arch Phys Med Rehabil 2005;86(12 Suppl 2): S115-20.

Objective: To compare stroke rehabilitation practice and outcomes between New Zealand (NZ) and the United States.

Design: Prospective observational cohort study.

Setting: Seven inpatient rehabilitation facilities (IRFs) in the United States and NZ.

Participants: Consecutive convenience sample of 1161 patients in 6 U.S. IRFs and 130 in 1 NZ IRF (age, >18y) after acute stroke.

Interventions: Not applicable.

Main Outcome Measures: Change in FIM score and discharge destination.

Results: NZ participants were older than U.S. participants (mean: 74.1y vs 66.0y, respectively; $P<.001$). Measures of initial stroke severity were higher for U.S. participants. Mean rehabilitation length of stay (LOS) was shorter for U.S. participants (18.6d vs 30.0d, $P<.001$), but physical and occupational therapy time per patient was considerably higher despite the shorter LOS. U.S. therapists were involved in more active therapies for more of the time. Outcomes were better for U.S. participants, with fewer discharged to institutional care (13.2% vs 21.5%, $P=.006$) and larger changes in FIM scores.

Conclusions: U.S. participants with acute stroke who were selected for rehabilitation had better outcomes than NZ participants, despite shorter stays in the rehabilitation facility. U.S. participants had more intensive input from physiotherapists and occupational therapists, which may explain some of the larger increases in FIM scores. This suggests that further studies with tighter controls on case mix may add additional information on the effects of therapy intensity on patients with stroke.

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STROKE REHABILITATION is a complicated undertaking. Convincing evidence exists for the use of specialized stroke rehabilitation,[1] but little evidence currently exists to help stroke rehabilitation clinicians determine exactly how the details of stroke rehabilitation should be practiced. As a result, it is inevitable that different stroke rehabilitation teams will operate in different ways. These differences might be especially noticeable across different health systems, because stroke rehabilitation services react to various incentives and disincentives in an effort to provide the best care they can within resource constraints for the patients whom they manage. A comparison of the structures, processes, and outcomes of stroke rehabilitation services across different health systems might tell us much about what is important in stroke rehabilitation and give clinicians and funders in those systems information to guide future change.

Few attempts at international comparisons of stroke management have been published. The most ambitious project comparing stroke outcomes across international borders has been with the BIOMED studies in Europe.[2] These researchers attempted to relate marked differences in stroke mortality and dependency to differences in stroke practices across countries, combining acute and postacute phases of stroke care and making allowances for case mix as permitted by the quality of the data collected. Those studies looked only at broad differences in practice, generally in the acute phase of care.

A comparison of the UK National Health Service (NHS) and the United States (using data from Kaiser Permanente in California, Medicare California, and U.S. Medicare as a whole) was made with stroke care as 1 key diagnosis.[3] This suggested that for people aged 65 years and older, admissions rates for stroke were broadly similar (NHS, 823/100,000; Kaiser, 788; Medicare California, 1155; U.S. Medicare, 1183). Mean lengths of stay (LOSs) were markedly different (NHS, 27.1d; Kaiser, 4.3d; Medicare California, 5.8d; U.S. Medicare, 6.5d). However, as pointed out by various commentators,[4] the analysis was significantly flawed: for the UK, postacute (ie, rehabilitation) care was included, whereas for the U.S. data, it was not.

New Zealand (NZ) has a public health system modeled on that of the UK, and the Post-Stroke Rehabilitation Outcomes Project (PSROP) provides an opportunity to compare stroke rehabilitation resource use and outcomes, adjusted for case mix, that was not possible in the analysis of Ham et al.[3] We know of no previous attempt to compare inpatient stroke rehabilitation practice between different countries. Previous comparisons of stroke rehabilitation practice across different hospitals but within the same health system have been at the level of retrospective audit of practice, comparing this with short-term outcomes.[5,6]

The PSROP, which includes 6 U.S. sites and 1 NZ site, allows the opportunity to compare stroke rehabilitation practice between the 2 countries at a high level of detail with prospectively obtained data and standardization of data input and outcomes.

We aimed to identify differences in stroke rehabilitation practice between U.S. rehabilitation facilities and NZ hospitals and determine whether these differences affected outcomes at hospital discharge. The null hypothesis was that despite major differences in resource use between the 2 health systems for stroke rehabilitation, for people with stroke admitted to a rehabilitation facility, outcomes in terms of disability and institutionalization at hospital discharge would be similar once allowance was made for stroke case mix.

Stroke Epidemiology and Services in NZ Versus the United States

With what published information is available, it is possible to say that stroke prevalence is broadly similar between NZ and the United States. For people aged 65 years and older in the United States, stroke prevalence was approximately 45 cases per 1000, and in NZ it was 48 cases per 1000.[7] Both populations have dominant white majorities with minority populations that have a higher prevalence of important stroke risk factors and stroke incidence. There is evidence from NZ that Maori and Pacific people who survive a stroke have worse case-mix adjusted outcomes at 12 months than for European New Zealanders.[8] There is also evidence that a similar relation may hold for ethnic minorities in the United States.[9] In both countries, hospital admissions for stroke have increased and stroke mortality has declined over the last 20 years.

In NZ, specialized stroke units for acute care and/or rehabilitation of stroke are rare,[10] and the Wellington site involved in this study did not provide stroke unit care. Wellington is the capital city of NZ, and the health district provides services for about 250,000 people. There are 2 general hospitals, one of which is a university teaching hospital with tertiary services. About 90% of people with acute stroke in NZ are admitted to hospital, generally to a general medical ward.

Average LOS for an acute stroke admission in Wellington is about 7 days. During this acute stay, patients are assessed by members of a rehabilitation service and managed in 1 of 3 ways: likely to die in hospital (managed for whole admission in general medical ward), needs long-term institutional care and unlikely to benefit from short-term inpatient rehabilitation (discharged to institutional care), and may benefit from short-term inpatient rehabilitation (transferred to inpatient rehabilitation service). In Wellington, about 40% of all acute stroke admissions are transferred for inpatient rehabilitation. Depending on where a patient with stroke lives geographically, he/she is managed in 1 of 2 inpatient rehabilitation units, separated by 20km but managed by the same service along similar lines. Inpatient rehabilitation involves intense multidisciplinary team input, and patients are selected on the basis of their ability to participate in an active program of rehabilitation. However, there is no requirement that an arbitrary amount of clinician input (eg, 3h/d) be delivered.

All the hospital care (acute and rehabilitation) is provided free to patients as part of the NZ public health system. Outpatient rehabilitation is also free and provided for a limited time, generally less than 12 weeks.[11] Institutional care is provided with a cost to patients, although this is means tested, and a full government subsidy is provided for about 50% of all patients. Long-term care institutions provide a very limited amount of rehabilitation clinician input—for example, at most 1 hour of physiotherapy (PT) per week and usually no occupational therapy (OT), speech and language pathology (SLP), or social work input. Medical input is from family doctors. There is no equivalent of the skilled nursing facility (SNF) in NZ. This leads to a situation where patients, initially unable to tolerate intensive rehabilitation, might still be admitted to a rehabilitation facility before any consideration of long-term care as an option. In terms of acute and rehabilitation LOS, intensity of inpatient and outpatient rehabilitation, and general rehabilitation practice, Wellington is representative of what happens to people with stroke in most larger centers in NZ.[10]

In the United States, the trajectory of stroke care is somewhat different. After a brief stay in an acute care hospital, patients with stroke typically will be triaged to 1 of several locations: home, a hospital-based rehabilitation center if they are medically stable and can tolerate at least 3 hours of therapy a day, or an SNF if they have not achieved medical stability and are unable to tolerate a full dose of rehabilitation therapy. Those who are discharged home may receive home-based rehabilitation from a home health agency or may receive rehabilitation therapy at a rehabilitation outpatient center. Finally, some will be discharged to a nursing home if they are severely impaired and believed to be unable to benefit from rehabilitation. The transfer to one of these postacute settings is not always systematic and may depend in part on the preferences of a health plan and the advocacy skills of family members. Overall, the setting for postacute stroke rehabilitation will vary with each patient's needs, health plan, family preferences, and geographic location, because types of postacute facilities vary from one part of the United States to another for reasons related to history, degree of urbanization, and the vagaries of local health care markets. Because most stroke survivors are older, they are eligible for Medicare, which remains the dominant payer of stroke rehabilitation services in the United States.

METHODS

The methodology governing the full PSROP, provided in this supplement by Gassaway et al,[12] provides a detailed description of the larger study's participating facilities, patient selection criteria, data collection instruments including their validity and reliability, and a detailed description of the project's final study group. The methodology is summarized in Maulden et al.[13] The institutional review boards at Boston University and at each participating inpatient rehabilitation facility (IRF) approved the study. NZ participants, along with those from 1 U.S. site, gave written consent for a 6-month telephone follow-up.

Wellington was the only non-U.S. site in the PRSOP, comprising 2 rehabilitation facilities that are geographically separated by 20km but are managed by the same overall service along similar lines. All study documentation was identical for both NZ and U.S. participants, with any uncertainties about labeling of specific activities and interventions by different therapists and nurses resolved by discussion with members of the study committee. The data manager for the NZ site (responsible for data extraction from clinical files) was trained in the United States along with U.S. site data managers and remained in close contact with the project manager throughout the study period.

Analysis

Categoric variables were analyzed using the Fisher exact test or chi-square test, and continuous variables were analyzed by *t* test where assumptions of normality were met.

Table 1: Demographic Characteristics and Prestroke Variables

Demographic Characteristics	NZ (n=130)	U.S. (n=1161)	P
Mean age ± SD (y)	74.1±12.6	66.0±14.6	<.001*
Race (%)			<.001†
White	83.1	58.1	
African American	0.0	25.8	
Hispanic	0.0	7.7	
Maori/Pacific	10.8	0.9	
Asian	5.4	5.9	
American Indian	0.0	0.8	
Uncertain	0.8	1.0	
Men (%)	51.5	51.9	1.00†
Health and functional characteristics			
Prior stroke (%)	28.5	27.9	.920†
Hypertension diagnosis (%)	74.6	78.6	.310†
Diabetes diagnosis (%)	20.1	30.8	.020†
Current smoker (%)	24.6	20.9	.190†
Mean weight ± SD (kg)	71.8±16.3	77.0±18.4	.007*
ADL independent before stroke (%)	85.4	91.0	.002†
Ambulant without assistance or device before stroke (%)	73.1	84.1	.005†
Lived alone before stroke (%)	32.3	20.7	.004†

Abbreviation: SD, standard deviation.
*t test.
†Chi-square test.

RESULTS

There were 130 participants from NZ and 1161 participants from U.S. centers for comparison. The NZ population was significantly older (74.1y vs 66.0y, $P<.001$), less ethnically diverse (83.1% vs 58.1% white, $P<.001$), and more dependent before the stroke (dependent for activities of daily living [ADLs], 14.6% vs 9%, $P=.002$; dependent for ambulation: 26.9% vs 15.9%, $P=.005$) (table 1). Patients with stroke in NZ were also more likely to be living alone before their strokes (32.3% vs 20.7%, $P=.004$). Important stroke risk factors were similar in the 2 populations except for diabetes, which was more common in U.S. participants (27.7% vs 20.1%, $P=.02$) and mean weight, which was higher in U.S. participants (77.0kg vs 71.8kg, $P=.007$).

Measures of stroke severity (table 2) at the time of maximum extent were somewhat similar between the 2 populations, including proportion with hemorrhages, proportion with aphasia, complete hemiplegia, and inability to walk. There was a surprisingly big difference in the diagnosis of depression (NZ, 0.8% vs U.S., 12.5%; $P<.001$) and "any mental health disorder" (NZ, 9.2% vs U.S., 54.9%; $P<.001$) between the 2 groups, which may reflect a combination of different thresholds for the diagnosis of a mental health disorder and/or a different level of likelihood that such a diagnosis is documented.

At the time of admission to the rehabilitation facility, U.S. participants had nonsignificantly lower mean FIM scores (U.S., 61.0 vs NZ, 65.6) and significantly higher (worse) Comprehensive Severity Index (CSI) scores (U.S., 20.7 vs NZ, 15.6; $P<.001$) based on the continuous rather than the discrete 4-point version of the CSI.

Regarding the practice of rehabilitation in the different populations, there was a significantly shorter mean delay from stroke onset to rehabilitation admission for NZ participants (11.5d vs 13.8d, $P=.011$), although this was affected in part by a bimodal distribution for the U.S. participants, where the majority had a short delay (U.S. median delay, 7d vs NZ median delay, 9.5d) but others had a substantial delay (eg, entering the rehabilitation facility after a period in an SNF) (table 3).

There was evidence of more intervention in the rehabilitation stay for U.S. participants for feeding (tube feeding: U.S., 16.9% vs NZ, 7.7%; $P=.005$) and oxygen (U.S., 16.5% vs NZ, 5.4%; $P<.001$). The mean rehabilitation LOS was significantly shorter for U.S. participants (18.6d vs 30.0d, $P<.001$), but during that time, more time was spent with a physiotherapist (U.S. mean, 800min vs NZ mean, 460.1min; $P<.001$) and occupational therapist (U.S. mean, 715.0min vs NZ mean, 208.4min; $P<.001$). U.S. participants were seen by a physiotherapist and occupational therapist on a larger proportion of the days that they spent in the rehabilitation facility (mean PT days/mean days in rehabilitation: U.S., 13.5/18.6d vs NZ, 13.3/30d; mean OT days/mean days in rehabilitation: U.S., 11.7/18.6d vs NZ, 5.8/30d).

Because therapists recorded what they did while working with participants, it is possible to make some comments about the actual components of rehabilitation practice within disciplines in the 2 systems.

NZ physiotherapists spent a greater proportion of their time than their U.S. counterparts (table 4) with participants engaged

Table 2: A Comparison of Variables Describing the Extent and/or Consequences of Stroke

Stroke Variable	NZ (n=130)	U.S. (n=1161)	P
Hemorrhage (%)	20.0	23.3	.44§
Nonambulatory at max extent of stroke (%)	62.8	54.1	.09§
Complete hemiplegia (%)	7.7	12.8	.12§
Aphasia (%)	20.0	21.8	.74§
Depression in acute or rehab admission (%)	0.8	12.5	<.001§
Any mental health disorder (%)	9.2	54.9	<.001§
Mean admission to rehab FIM score ± SD			
Total	65.6±28.6	61.0±20.3	.09†
Motor	43.3±21.1	40.1±14.7	.11†
Cognitive	22.3±10.7	21.0±8.3	.17†
CMGs at rehabilitation admission (%)*			<.001§
Mild (CMG 101–103)	32.5	10.0	
Moderate (CMG 104–107)	20.3	44.8	
Severe (CMG 108–114)	47.2	45.2	
Mean discrete CSI ± SD‡	1.28±0.70	1.45±0.63	.005†
Mean rehab admission continuous CSI ± SD‡	15.6±10.5	20.7±13.7	<.001†
Mean increase in severity during admission (max − admission CSI) ± SD‡	10.4±13.0	10.7±11.7	.80†

Abbreviations: CMG, case-mix group; CSI, Comprehensive Severity Index; rehab, rehabilitation.
*Based on CMGs used by the U.S. Centers for Medicare and Medicaid Services in determining amounts of payment under Medicare's prospective payment system for IRFs.
‡For a fuller description of the CSI, see Gassaway et al.[12] Higher scores indicate worse condition.
†t test.
§Chi-square test.

Table 3: Comparison of Process Variables for Inpatient Stay of NZ and U.S. Participants

Process Variables	NZ (n=130)	U.S. (n=1161)	P
Mean onset to rehab admission ± SD (d)	11.5±7.5	13.8±20.8	.011*
Mean acute LOS ± SD	10.4±6.3	8.6±8.4	.004*
Mean rehab LOS ± SD	30.0±19.6	18.6±10.6	<.001*
Mean PT days in rehab ± SD	13.3±11.4	13.5±8.1	.800*
Mean PT minutes in rehab ± SD	460.1±543	800±548	<.001*
Mean OT days in rehab ± SD	5.8±5.2	11.7±7.6	<.001*
Mean OT minutes in rehab ± SD	208.4±265	715.0±537	<.001*
Acute stay tube feed (%)	6.9	21.7	<.001†
Rehab stay tube feeding (any) (%)	7.7	16.9	.005†
Oxygen during rehab stay (%)	5.4	16.5	<.001†

*t test.
†Chi-square test.

in assessment activities and lower-level mobility activities (bed mobility, sitting balance, sit to stand), whereas U.S. therapists spent a greater proportion of their time in higher-level mobility activities (transfers, pregait, gait, advanced gait).

NZ occupational therapists spent a large proportion (NZ, 49.4% vs U.S., 10.7%; $P<.001$) of their time in assessments both in the facility and home. In NZ, a home visit before discharge is virtually routine and usually is conducted by the occupational therapists. Occupational therapists are also responsible for much of the cognitive testing, because psychologists are rarely available or used. On the other hand, U.S. occupational therapists spent a considerable portion of time with participants working with the upper limb, usually the domain of the physiotherapists in NZ.

NZ speech-language therapists spent most of their time with participants involved in assessment of or activities around swallowing (NZ, 50.7% vs U.S., 19.3, $P<.05$), whereas U.S. speech-language therapists spent most of their time in activities around expression, comprehension, and cognitive activities.

Overall, NZ therapists spent more time in assessment and nonfunctional activities than their U.S. counterparts. Nonfunctional activities are activities not directly related to the functional enhancement of a patient or time spent on a patient's behalf but not in direct contact with the patient (eg, time selecting and ordering a wheelchair or splint).

Outcomes at hospital discharge were better for U.S. than NZ participants (table 5). For U.S. participants, fewer participants were discharged to institutional care (U.S., 13.2% vs NZ, 21.5%; $P=.006$), there was a higger increase in FIM score during admission (U.S., 26.2 vs NZ, 20.6; $P<.001$), and the change in CSI score was greater (U.S., 10.2 vs NZ, 5.6; $P<.001$). It is possible that the criteria for admission to institutional care in the 2 countries may be different. However, it is possible to say that levels of disability at rehabilitation discharge were very similar, with mean FIM scores within 2 points of each other (U.S., 87.2 vs NZ, 85.6; $P=.57$).

DISCUSSION

Our results show that significant differences exist for stroke rehabilitation practice and outcomes for participants in NZ and U.S. rehabilitation facilities. NZ participants tended to be older, frailer, and more likely to live alone before stroke, but U.S. participants scored somewhat worse on measures of disability and comorbidity at the beginning of stroke rehabilitation. U.S. participants stayed a much shorter time in the rehabilitation facility but had much higher input from PT and OT in that time, both in terms of tbe proportion of days on which they were seen and the total number of minutes of time.

U.S. participants had better outcomes, with more rapid change in disability scores and a lower chance of discharge to

Table 4: Comparison of the Components of Rehabilitation Practice: PT, OT, and SLP

Activity	Percent of Total Time Spent in Each Class of Activity: NZ	U.S.	P
PT			
Assessment	15.7	9.6	.001*
Movement activities before transfers	32.4	24.3	<.001*
Movement activities, transfers, and walking	38.7	54.0	<.001*
Nonfunctional time	23.3	21.5	.400*
OT			
Assessments	49.4	10.7	<.001*
ADLs	30.5	31.0	.870*
Mobility activities including transfers and wheelchair	13.0	20.1	.016*
Working with upper limb	0.9	24.6	<.001*
Home management, leisure, and community integration	9.5	12.9	.147*
Nonfunctional activities	18.8	10.6	.014*
SLP			
Assessment	26.9	19.3	.100*
Swallowing	50.7	19.3	<.050*
Voice and expression activities	30.8	31.2	.940*
Comprehension activities	6.4	14.4	<.001*
Memory, problem solving, and other cognitive activities	2.4	33.3	<.001*
Nonfunctional activities	8.5	1.1	<.050*

*t test.

Table 5: Comparison of Outcomes for NZ and U.S. Participants

Outcome Variables	NZ (n=130)	U.S. (n=1161)	P
Discharge destination, n (%)			.006*
Home	92 (70.8)	906 (78.0)	
Community assisted living	3 (2.3)	34 (2.9)	
Institutional	28 (21.5)	153 (13.2)	
Hospital	1 (0.8)	47 (4.1)	
Other acute rehab	3 (2.3)	15 (1.3)	
Died	3 (2.3)	6 (0.5)	
Mean discharge FIM score ± SD	85.6±30.7	87.2±22.5	.570†
Mean increase in FIM score ± SD	20.6±15.2	26.2±14.0	<.001†
Mean net medical improvement (admission − discharge CSI) ± SD‡	5.6±14.5	10.2±10.7	<.001†
Mean rehab discharge CSI continuous scores ± SD‡	10.0±16.0	10.5±12.6	.600†

*Chi-square test.
†*t* test.
‡For a fuller description of the CSI, see Gassaway et al.[12] Higher scores indicate worse condition.

institutional care. These differences occurred despite the increased severity of U.S. participants' disabilities at the time of their rehabilitation admissions.

The components of rehabilitation practice for different types of therapists were surprisingly different between NZ and U.S. facilities. U.S. therapists of all types spent a smaller proportion of their time in assessment and nonfunctional activities and proportionately more time in active management of participants. This was particularly so for occupational therapists. U.S. occupational therapists spent almost a quarter of their time involved in activities with the upper limb, an activity rarely performed by NZ occupational therapists and more often performed by NZ physiotherapists, as noted earlier. Speech-language therapists in NZ spent more of their time involved in swallowing activities than the more traditional speech and language activities, whereas U.S. speech-language therapists provided significant input into cognitive activities.

There are some major questions that might affect the interpretation of these results. First, how representative of NZ and U.S. practice are the facilities studied? Certainly, the NZ facility falls somewhere in the middle of NZ rehabilitation facilities for efficiency (rehabilitation LOS), and the staffing is broadly similar with other units in the country. The 6 U.S. facilities in the PSROP are a geographically diverse group of IRFs, and based on comparisons with a more nationally representative group of IRFs,[14] these 6 facilities serve a somewhat nationally representative sample of stroke rehabilitation patients served in IRFs.

Second, how much difference does the age disparity between the U.S. and NZ study groups make on outcome, particularly institutionalization? One could argue that the older population studied in NZ was at higher risk of poststroke rehabilitation institutionalization. For study participants as a whole, increasing age was only very weakly associated with institutionalization. In an earlier NZ study, age was not a significant independent variable in rate of change of disability in hospital for people with stroke,[14] suggesting that the age difference cannot be the sole explanation for the differences in practice patterns and outcomes reported here.

The cause of the age disparity needs to be considered, because this may suggest important unmeasured covariates in outcome. With the availability of additional postacute rehabilitation venues such as SNFs in the United States, it is possible that older patients with stroke in the United States are more likely to be managed in an alternative postacute setting than those in NZ. One consequence of this is that in NZ, a significant proportion of elderly people with stroke will be "given a go" in a rehabilitation facility, with a fairly high expectation of the need for eventual institutional care rather than for discharge direct from an acute hospital to the institutional setting. NZ lacks SNFs either as an alternative to an IRF or as an intermediate step on the way to an IRF. It could be argued that such facilities might inadvertently help improve the effectiveness and efficiency of rehabilitation facilities by enabling IRFs to work with patients who are more likely to succeed with IRF-level care. Thus, in the U.S., hospital-based rehabilitation facilities may be less likely to admit patients with any risk of not being discharged to home. This would have the effect of reducing the age of the population admitted to an IRF and providing a small advantage in favor of discharge home compared with NZ participants. Published U.S. data from 1999 show a mean age for patients with stroke admitted to IRFs of 70 years,[15] whereas that for patients with stroke admitted to subacute rehabilitation facilities (mainly SNFs) was 76 years,[16] suggesting some sort of selection process related to age. Nevertheless, age aside, the severity indicators in this study, which included various comorbid conditions, favored the NZ participants.

The higher proportion of NZ patients living alone before their strokes may have influenced more to be discharged to institutions. The NZ mean discharge FIM score of 85.6 indicates that a large proportion of those discharged required continued assistance. The relatively similar discharge FIM and CSI scores at discharge for the 2 patient groups would suggest that the differences were not due to clinical factors.

There is an increasing body of evidence that increasing the intensity of stroke rehabilitation improves outcomes,[17,18] and this study supports that notion. Although the case mix of these compared populations had differences, an analysis of these differences tends to support the conclusion that increased therapy intensity results in more rapid functional improvement in patients early after stroke. The difference in the rate of change of FIM scores between the groups was substantial. As discussed earlier, previous studies found that age had little effect on these rates of change. It seems possible that medical severity could delay functional recovery, yet it was greater in the U.S. population, which showed the fastest and greatest improvement. The discharge FIM scores of the 2 groups were not significantly different, so the prestroke differences in function do not seem to have had substantive effects. The closeness of the admission FIM scores suggests that the ceiling effects of the FIM had little influence. Living alone before admission should not influence functional capacity. Depression and mental health disorders would be more likely to slow rather than increase improvement rates. Although further studies on more closely matched populations may be needed to ultimately clarify the impact of more intense therapy, the evidence strongly suggests that more intensity can result in greater and more rapid gains in appropriately selected patients with stroke.

CONCLUSIONS

This study shows that it is not only the total hours of therapy that are important but what happens during the therapy session. Rehabilitation services that manage people with stroke should consider the level of intensity of therapy input and concentrate on active therapy. For NZ services, an overemphasis on assessment may contribute to delays in initiating active therapy, leading in turn to longer-than-necessary stays in a hospital.

Given the therapy intensity for U.S. patients observed in this study, there may be ample opportunity to increase therapist input for NZ patients on more days during a rehabilitation stay. The NZ public health system has tended to focus too much on overall costs without examining the components of those costs that make a difference. Practices to promote efficiency, or better outcomes if they involve new spending (eg, such as more staff or staff working on 6 days rather than 5), have been difficult to implement. The results reported here provide some focus for a change in mindset that should benefit patients with stroke. It should be noted, however, that the costs of inpatient rehabilitation in the 2 countries are massively different—for NZ, the per-day cost is around US$320, whereas U.S. rehabilitation facilities charge around US$1050/d. Even with a much shorter LOS, the mean total cost of a rehabilitation stay in a U.S. facility is almost double that in NZ. Depending on one's perspective (eg, patient, clinician, funder), the difference in outcomes reported here may or may not represent good value.

The other lesson from this study is that there is much to be learned from rehabilitation practitioners in different countries and different parts of the same country if robust study methods and analysis can be adopted. We note with interest a European study hosted at the Free University of Brussels with design elements similar to this study. That study, known as the Collaborative Evaluation of Rehabilitation in Stroke Across Europe, is investigating stroke rehabilitation practice in 4 European countries. Incorporating the best elements from many service delivery models may provide a rapid way to achieve better outcomes for people with stroke.

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COMMENTARY

The Post-Stroke Rehabilitation Outcomes Project

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ABSTRACT. Ottenbacher KJ. The Post-Stroke Rehabilitation Outcomes Project. Arch Phys Med Rehabil 2005;86(12 Suppl 2):S121-3.

The Post-Stroke Rehabilitation Outcomes Project (PSROP) examined a large sample of patients from multiple facilities receiving inpatient stroke rehabilitation services. This commentary describes strengths and potential limitations of the investigation including selection bias, observation bias, confounds, and interpretation. The PSROP is an important study that will advance our understanding of effective treatment for persons with stroke.

Key Words: Rehabilitation; Stroke.

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THE POST-STROKE REHABILITATION Outcomes Project (PSROP) is an important study on a major public health problem.[1] The World Health Organization projects that stroke will become a leading cause of mortality worldwide in this century.[2,3] More than 50% of those 65 years and older who survive a stroke report hemiparesis at 6 month follow-up. Thirty percent of persons (≥65y) are unable to walk without assistance and 26% are dependent in at least 1 basic activity of daily living 6 months poststroke.[1] The social and economic impact of stroke are well described by DeJong et al[4] and demonstrate the need for the PSROP.

During the past 2 decades, dramatic improvements have been made in the treatment of stroke and convincing scientific evidence now exists that stroke rehabilitation programs are effective. The evidence on overall efficacy is summarized in *Recovery After Stroke*[5] and other recent publications.[6,7] What we do not know is which patients are the best candidates for the complex array of rehabilitation methods and techniques currently available.[6] DeJong refers to this problem as the "black box" of stroke rehabilitation and notes: "the interaction between each stroke survivor, his/her comorbidities, personal behaviors, and coping abilities and all of these health care providers and family members is complex and highly specific—with each and all factors having a possible impact on the patient's outcome."[4(p2)] The PSROP investigators should be congratulated on their efforts to examine systematically the black box of stroke rebabilitation, including the complex interactions among patient characteristics, treatment approaches, and rehabilitation outcomes.

The method they have selected, clinical practice improvement (CPI), is an innovative and powerful approach designed to examine complicated research questions in a real-world setting. The findings are presented as a series of observational "cohort" investigations that represent a descriptive epidemiology of stroke rehabilitation. The strengths of the approach are the relevance to real-world clinical practice, the focus on the care management process, the inclusion of a wide range of patients, the collection of a large amount of treatment and outcome data, and the active participation of front-line clinicians in the planning and implementation of the study. These factors all add to the ecologic validity of the PSROP.

Regarding internal validity, the authors discuss several recent investigations[8,9] comparing outcomes for randomized controlled trials (RCTs) and observational studies. These studies suggest that well-described cohort and case-control investigations produce results that are similar to RCTs. These investigations, however, examined cohort and case-control studies that involved comparison or control groups, masked recording of outcomes, and included dependent measures with established reliability and validity. As an observational study, the PSROP does not include many of these design features. The PSROP results must be carefully examined in relation to the potential limitations associated with observational investigations. This is particularly true in view of the absence of a comprehensive description of the limitations of the PSROP. In discussing the combined series of analyses included in the PSROP, the only limitation identified in the article by DeJong[4] is the failure to collect follow-up data across all the participating sites.

The remainder of tbis commentary describes potential limitations associated with observational studies and briefly discusses how these relate to the PSROP. My comments are directed at areas of potential concern relevant to prospective cohort studies. These concerns are selection bias, observational bias, confounds, and interpretation.

SELECTION BIAS

Selection bias occurs when there is a preferential inclusion of subjects with certain treatment outcomes.[10] In cohort studies, this usually occurs when information is less likely to be collected or analyzed from subjects who have better (or worse) outcomes. In the PSROP, the potential for selection bias is subtle because 2 cohorts (eg, treatment vs control) were not followed. In several of the analyses reported in the PSROP, however, 1 subgroup of patients is compared with another subgroup. For example, patients who received early therapy were compared with patients receiving later therapy, or patients receiving new antidepressant drugs were compared with patients administered older medications. In some cases, patients in various case-mix groups were selected for analysis and others were excluded. Patients in these subgroups may have differed in ways unknown to the investigators and not adjusted for in the statistical analyses (see Confounds below).

OBSERVATION BIAS

Observation or information bias is associated with measurement error that can be introduced in various ways.[10] One strength of the PSROP is the involvement of front-line clinicians in the development of the data collection instrument and actual data gathering and recording. The participation of ther-

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apists ensures the outcomes will be clinically relevant, but also introduces a potential bias. The therapists collecting and recording data are aware of the study, its purpose, and its goals, and this may (unconsciously) affect how they treat patients and/or record data. This is frequently referred to as the Hawthorne or experimenter effect, and there is a large literature on how it can impact study outcomes.[11,12] Observation bias is known to be a potential problem in stroke rehabilitation cohort-type investigations. A previous meta-analysis[13] of stroke rehabilitation studies found an interaction between design quality and study outcome that was moderated by whether or not the outcome was blindly recorded. There was no difference in outcomes between RCTs and nonrandomized studies when both sets of trials used blind recoding of the primary outcome. There were significant differences, however, when blind recording was not used, with the nonrandomized cohort studies reporting larger effect sizes and more statistically significant results.

Another area of observation bias that deserves mention relates to recording large amounts of data from medical records. No information on the accuracy or consistency of abstracting this information from the medical or other health care records is provided.

CONFOUNDS

Confounding occurs when 2 factors are associated with each other, and the effect of one is confused with or distorted by the effect of the other. Confounding variables differ from effect modifiers or moderator variables, but both influence outcomes.[10] Confounding variables are usually controlled by manipulation of the study design or statistical methods. In the PSROP, confounding is controlled statistically. Statistical control requires that the confounding variables are known and measured. In clinical cohort studies, there are usually not enough subjects included or variables measured to statistically control for many confounding factors. Strengths of the CPI approach include the recruitment of a large and heterogeneous sample of patients and measurement of a substantial number of potential confounding variables. The Comprehensive Severity Index (CSI) was used to control for differences in patient severity of illness, including comorbidities. The CSI is described as an age- and disease-specific measure of physiologic and psychologic complexity comprised of over 2000 signs, symptoms, and physical findings.[14] Little operational detail is provided about the CSI and its use in stroke rehabilitation. The cited references focus on acute care hospitalization with an emphasis on pediatrics. We do not know what variables went into the CSI, how the variables were weighted, or how missing data were handled. In the results from the summary article on early and more aggressive therapy,[15] the CSI did not enter into several of the regression equations, suggesting that admission FIM and other severity-related variables shared substantial variance with CSI scores. The usefulness of the CSI relative to other potential severity adjustors such as function-related groups, and admission FIM instrument motor and/or cognitive ratings requires further investigation, particularly in view of the investigator and/or respondent burden for collecting the substantial amount of information required by the CSI.

In some analyses, general statements are made that variables were controlled for in the regression equations, but the method of control is not always clear. We do not know the ratio of variables to subjects, if interactions were tested, or if all assumptions were met for complex regression models. While the overall sample is relatively large for a clinical study, many of the regression analyses appear to include smaller numbers of subjects. More than 120 variables are listed in appendix 1, yet some of the regression models described in table 8 include fewer than 120 subjects.[15]

INTERPRETATION

A final issue involves the level of inference that can be drawn from the data collected and analyzed in the PSROP. The article by Horn et al[15] includes an excellent discussion comparing and contrasting RCTs and observational studies. I agree with the need for a broader approach to research design and the inclusion of methods other than RCTs in the generation of evidence-based knowledge for rehabilitation. While I am sympathetic to the idea that there are multiple approaches to establishing valid scientific information, we must recognize the limitations on inferences that can be drawn from a single observational study. Observational investigations, including the PSROP, provide data on associations among variables. These associations are important and can lead to improvements in practice if they are replicated and validated. Data from a single observational study do not allow the investigators to make causal inferences.[10] There are many statements in the PSROP articles that imply causality. This confusion about association versus causation is reflected in the statement of the PSROP's principle research question presented by DeJong et al: "[W]hat *impact* does each stroke rehabilitation activity or intervention, both individually and collectively, have on patient outcomes on discharge controlling for patient differences including medical and functional status on admission? (emphasis added)."[4(p3)] Based on the PSROP design, this question would be better phrased as, "What is the association between each stroke rehabilitation. . . ." There are numerous instances where "impact," "affect," "influence," and "responsible for" are used to describe the connection between variables and outcomes. There are also many examples throughout the articles where the terms *association* and *relationship* are used appropriately. Cumulatively, however, the inconsistent use of terms implying both causation and association contribute to the authors' proposing recommendations for changes in practice that, in my opinion, are premature based on associational data from 1 study (sample).

The issues of interpretation and implications for clinical practice are directly related to establishing a research foundation for evidenced-based rehabilitation. The evidence provided by the PSROP investigation would be considered level 3 or 4 using the Center for Evidence-Based Medicine criteria.[16] The importance of using appropriate levels of evidence to guide clinical practice has recently been illustrated in the radical change in practice recommendations on the use of hormone replacement therapy in postmenopausal women. Practice guidelines changed dramatically when large randomized trials did not support the findings of earlier observational studies.[17]

CONCLUSIONS

The limitations outlined above are essential to consider in evaluating the PSROP findings, but they should not detract from the importance of this research effort. The PSROP is an impressive and valuable addition to the scientific literature in stroke rehabilitation. The study provides crucial new findings and expands our understanding of the rehabilitation process applied to persons with stroke. We are all keenly aware that any investigation, particularly one as large and complex as the PSROP, will have limitations. These limitations should be recognized in order to help interpret the findings and better plan future research. The PSROP investigators have opened the lid of stroke rehabilitation's black box. Thanks to their efforts, we

have the opportunity to peer into the black box and begin the exciting challenge of exploring its contents.

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COMMENTARY

The Post-Stroke Rehabilitation Outcomes Project

Alan M. Jette, PT, PhD

ABSTRACT. Jette AM. The Post-Stroke Rehabilitation Outcomes Project. Arch Phys Med Rehabil 2005;86(12 Suppl 2): S124-5.

The Post-Stroke Rehabilitation Outcomes Project (PSROP) provides an important example of the value of observational study designs in rehabilitation. The strength of the PSROP lies in the extensive, in-depth data collected on the specific rehabilitation interventions provided to patients and their relationship to short-term outcomes as well as the wide generalizability of the study's findings. Although providing valuable insights, one has to be extremely cautious in drawing direct practice recommendations from the PSROP given several internal validity threats inherent in the PSROP design.

Key Words: Rehabilitation; Stroke.

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I CONGRATULATE DR. HORN and colleagues on the successful completion of their ambitious multicenter, multinational Post-Stroke Rehabilitation Outcomes Project (PSROP) and in organizing their major findings in this supplement of *Archives.*

In the interest of full disclosure, readers should know that the PSROP, an in-depth observational investigation of stroke rehabilitation practice variation and its relationship to short-term outcomes, was conceived and partially funded under the auspices the Rehabilitation Research and Training Center on Medical Rehabilitation Outcomes that I directed. I had the distinct privilege of collaborating with Horn and colleagues in the overall planning for the PSROP.

In this supplement, the authors address a critically important question faced not only in stroke rehabilitation but also in most areas of rehabilitation: What is the measurable impact of rehabilitation activities or interventions, both individually and collectively, on patient outcomes on discharge from inpatient rehabilitation care? There is great pressure on rehabilitation providers to demonstrate the effectiveness of what they do. Concerns over the rapidly escalating costs of postacute care have focused unprecedented attention on the concern that the rehabilitation services delivered to our patients may achieve at best only marginal improvements in health at a considerable cost. The pressure to control costs has prompted a call for better data on the outcome or effectiveness of rehabilitation care. The PSROP provides the rehabilitation field with an important additional method to respond to such calls.

The classic research approach to establishing the effectiveness of a particular health care service is to launch a carefully designed randomized controlled trial to evaluate the value of a particular service for a carefully defined group of patients. While this strategy can and is being used successfully in rehabilitation in an increasing number of areas, extending such an approach to all aspects of rehabilitation services would be prohibitively expensive, be difficult to mount, and take decades to achieve. An alternative approach, long employed in other areas of health care, is the use of observational designs. The basic analytic challenge in an observational design, such as the PSROP, is to assess the effectiveness of rehabilitation care by dissecting out the effects of treatment from the competitive effects of other factors, most notably, a patient's baseline status, relevant patient demographic and clinical factors, environmental factors, and competing treatment effects. The strength of such a design lies in the wide generalizability of the finding; the concern usually rests with how well it protects against major threats to the internal validity of the study's results.

The PSROP used a particular observational approach—clinical practice improvement (CPI)—developed by Horn. Although similar to most observational methodologies in its inclusion of broadly defined groups of patients and in its use of multivariate statistical analyses to dissect out the effects of treatment from other pertinent factors, in my view, this CPI methodology differs from other observational methodologies in the active collaboration of front-line clinicians in the planning as well as in the development of data collection instruments, in actual collection of the data, and in analysis and reporting of the findings. I believe the success of the PSROP depends heavily on the active involvement of front-line clinicians in each of the participating sites who contributed to the planning of the study design, development of the taxonomy used to characterize rehabilitation activities employed in the study, in collection of the data documenting stroke rehabilitation interventions, and in data analysis and interpretation.

The level of involvement of site clinicians was quite remarkable and a tribute to the skill of the research team as well as to the commitment of the participating clinicians. Aware of the limitations of using the medical record as the source of data to document the care provided to stroke patients, and the unavailability of existing standardized intervention documentation forms, the study's clinicians (ie, physicians, nurses, psychologists, social workers, and physical, occupational, recreational, and speech therapists) each created a standardized form to include the level of intervention specificity they believed was necessary to capture a complete and accurate picture of what was done by that discipline related to the rehabilitation care of each patient enrolled in the study. Each discipline developed its own content in collaboration with the PSROP study investigators and standardized the frequency with which the form would be completed. Protocols called for the intervention forms to be completed for each therapy session and nursing day for each study patient who was enrolled. The sheer volume of intervention data collected with these protocols is impressive. For the 1291 poststroke rehabilitation patients enrolled in the PSROP, a total of 141,511 forms were completed across all disciplines by clinicians who were involved in the PSROP. This is a remarkable achievement and provides the field with rehabilitation documentation protocols that are now available for fu-

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ture investigations. The key to their success with these forms, I believe, was the PSROP team's ability to give the participating clinicians ownership in the development of the data collection processes.

The PSROP investigators carefully attempted to standardize not only the documentation forms themselves but also their application. They trained participating clinicians in the use of the intervention documentation forms via discipline-specific train-the-trainer teleconferences attended by the lead clinicians from each facility. These lead clinicians trained others from their site. This training was supplemented with a training manual, detailed instructions, case studies, and definitions for all terms used on the forms. Unfortunately, data were not collected to verify the success of this impressive effort. We do not know if what clinicians recorded on the forms accurately represents what was actually done, whether the data recorded were complete, or the degree of consistency achieved across participating clinicians, or over time. These tasks were beyond the scope of what could be accomplished with the available funding. The field will have to await data from future studies to answer these important questions.

A second area that I would like to comment on is the conclusions that one draws from observational studies such as the PSROP. In the article by Horn et al,[1] the investigators report on the observed associations between over 100 patient characteristics, therapies, neurotropic medications, nutritional support, and the timing of rehabilitation with motor and cognitive functional outcomes and discharge destination. Horn focuses on 2 key findings that challenge conventional wisdom in rehabilitation practice. The first is that the more quickly a stroke patient starts inpatient rehabilitation after their stroke, the better the outcomes. Moreover, Horn reports that earlier gait activities, particularly in the first block of physical therapy (PT), have a significant effect on outcome regardless of how much additional therapy a patient receives.

Horn suggests that the findings argue for a more "aggressive approach" to PT and concludes that the results suggest that health care providers might need to shorten the duration from onset of stroke to onset of rehabilitation; to move patients as quickly as possible to higher-level, more difficult therapy activities.

I believe one has to be extremely cautious in drawing direct practice recommendations from the PSROP findings given several internal validity threats inherent in the PSROP design. With over 100 independent variables tested in several different multivariate models without specific a priori hypotheses, the risk of committing a type I error was considerable. Sample size limitations precluded the splitting of the sample into 2 random subsamples so that initial models could be built on 1 sample and replicated in a second subsample drawn from the same study sample. Second, the PSROP relied on the medical record as the primary source of data for many of the major clinical, demographic, and some treatment variables that were critical to controlling for potential confounding in their multivariate models. The lack of evidence of the completeness, reliability, and validity of these medical record data along with the legendary concerns about reporting and misclassification errors inherent in the medical record, gives me concern that some important potential confounding influences may have been inadequately identified and measured, and therefore not adequately controlled for in their analyses. A major concern is the probability that patients who received the early and more aggressive therapy were different from those who did not in ways that were also related to improved functional outcome. For example, provision of more aggressive therapy might have been related to the patient's motivation or level of perceived self-efficacy that might also be related to patient outcome. These psychologic factors were not measured in the study or available in the medical record and therefore could be an alternative explanation for the association between timing and type of therapy and the functional outcome. These internal validity concerns are common in observational designs such as the PSROP and argue for considerable caution in the extent to which action recommendations can be drawn from the findings of any 1 study.

I believe the findings of the PSROP reported in this supplement are extremely valuable. For me, the major implication of Horn's results is that their compelling finding related to the timing and nature of the PT interventions and more positive outcomes demand further testing and investigation. The associations need to be examined in different settings, with different samples of clinicians, and with different patients to enhance their internal validity. Until the major PSROS findings on the association of early and more aggressive therapy interventions with stroke patients can be replicated, however, I believe it is premature to advocate changes in practice patterns or policy changes.

The PSROP provides an important example of the value of observational study designs in rehabilitation, and I applaud the investigators for their important accomplishment, one that I hope is replicated by others. The PSROP provides us with an important additional method to respond to calls for the rehabilitation field to demonstrate the effectiveness of the services it provides.

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Project D2: **Metabolic Studies in Individuals with Chronic Spinal Cord Injury: The Effects of an Oral Anabolic Steroid and Conjugated Linoleic Acid**

Title: The Effects of a Trial with an Anabolic Agent in Healthy Persons with Tetraplegia: Case Series

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Abstract

The Effects of a Trial with an Anabolic Agent in Healthy Persons with Tetraplegia: Case Series

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Objective: Describe our experience in treating medically stable individuals with tetraplegia with an oral anabolic steroid.

Design: Prospective longitudinal treatment with oxandrolone in an outpatient setting.

Participants/methods: Oxandrolone 20mg/day was administered for 8 weeks to 10 subjects with motor complete tetraplegia. DEXA scans, pulmonary function tests (PFTs), serum lipids, and liver function tests (LFTs) were obtained at baseline and 4, 8, 12, and 20 weeks during and after treatment. Pre-and post-treatment differences were calculated and baseline values were compared to control and other tetraplegic populations.

Results: Mean lean body mass (LBM) increased by 4% in arms and 2% in total body while fat decreased by 0.7% in arms and 1.4% in total body during oxandrolone intervention. At 20 weeks, LBM increased another 7.5% in arms and 2% in total body. On average, weight increased 0.6 % and combined measures of PFTs improved 2.2% during treatment. High density lipoprotein (HDL-c) decreased 27%, low density lipoprotein (LDL-c) increased 32%, and LFTs increased 9.7-65 .6% while on therapy but trended to baseline at 20 weeks.

Conclusion: Treatment with oxandrolone in healthy subjects with tetraplegia was associated with modest improvement in PFTs and in arm and total body LBM which continued to increase at 20 weeks. Baseline body mass composition was similar to other reports for individuals with tetraplegia and with more fat and less LBM than in controls. Abnormal changes in serum lipids and LFTs during treatment indicate that reported benefits of using oxandrolone in this population must be carefully weighed against potential adverse effects, especially with long-term use.

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Introduction

Individuals with acute spinal cord injury (SCI) undergo a catabolic phase characterized by nitrogen wasting and loss of lean body mass (LBM). With time and the inactivity associated with SCI, significant changes in body composition occur with an increase in fat mass and a decrease in muscle mass. In addition to these changes, most individuals with SCI incur some degree of pulmonary insufficiency due to the neurologic impairment.

The acute loss of muscle mass is one contributing factor to the profound alterations in body composition seen in long-term SCI. Another factor is the reduction in body cell mass of 34% in paraplegics and 49% in tetraplegics.[1] Spungen *et al*.[2] used DEXA to assess body composition and found significant decreases in regional and total body lean tissue percentages in males with paraplegia and tetraplegia compared with controls. Overall, individuals with SCI can expect to lose approximately 3.2% of their total lean body mass (LBM) per decade compared with 1% per decade in the able-bodied population.[3]

In addition to a loss of LBM, most individuals with SCI incur some degree of pulmonary insufficiency. Linn *et al.*[4] quantified the loss of pulmonary function in subjects with SCI compared with able-bodied controls. Forced vital capacity (FVC) was 45% of predicted for those with C4 SCI, 81% of predicted when the injury was at the T5 level, and 95% of predicted for those with T12 SCI. This decreased pulmonary function results in pulmonary complications that are the most common cause of death and the second leading cause of morbidity in long-term SCI. [5, 6]

Anabolic steroids have been shown to reduce nitrogen wasting in HIV and severe burns and be beneficial in chronic obstructive disease (COPD). Preliminary data using one drug in this class, oxandrolone, suggest they might also be beneficial in reducing or minimizing some of the complications following SCI. A retrospective case series described 9 individuals with SCI who had non-healing pressure ulcers. After being treated with oxandrolone for 1 to 12 months (20mg/d) and glutamine, 8 of 9 patients had healed wounds.[7] In a small pilot study examining pulmonary function after a 1-month course of

oxandrolone (20mg/d), individuals with chronic SCI gained an average of 1.4 kilograms, had improved combined spirometry measures of 9%, and reported less dyspnea.[8]

The purpose of this report is to expand on this experience with oxandrolone and describe the effect of an 8 week course of 20 mg/day on body composition, BMI, and pulmonary function in tetraplegic subjects.

Methods

Subjects

Men with SCI were recruited from the outpatient clinic population at the National Rehabilitation Hospital using fliers and word of mouth. Eligible men were between the ages of 18 and 65, at least one year post injury, had a motor complete injury between C4 and C8, had access to reliable transportation, and could be readily reached by telephone. Individuals were excluded who had an active pulmonary infection or pressure ulcer, a history of liver disease, heart disease, diabetes mellitus, were taking warfarin, dantrolene sodium, carbamazepine or lipid lowering agents. Institutional review board (IRB) approval was obtained from the MedStar IRB and all subjects provided informed consent prior to enrolling in the study.

Design

Ten subjects took 20 mg oxandrolone daily in divided doses for 8 weeks. They were then followed for an additional 12 weeks. During this 20 week period, they were seen in the clinic on 5 occasions: week 1 (baseline), 4, 8, 12 and 20. Prior to taking the first dose of oxandrolone, the following baseline measurements were obtained: height and body weight, urinalysis, complete blood count, metabolic panel, lipid profile, a dual x-ray absorptiometry (DEXA), and pulmonary function tests (PFTs). The metabolic panel included the following liver function tests: serum aspartate aminotransferase (AST), alanine aminotransferase (ALT), lactic dehydrogenase (LDH), and albumin (ALB). The lipid profile included total cholesterol (TC), high density lipoprotein cholesterol (HDL-c), triglycerides (TRIG), and calculated low-density lipoprotein cholesterol (LDL-c). Except for height and urinalysis, these tests were repeated at each of the subsequent 4 visits.

The body mass index (BMI) was calculated by dividing the weight (kg) by the height (m^2). DEXA examinations provided measures of body composition for lean body mass (LBM) and body fat (BF) for the

total body and upper extremities. Using the BMI classification, subjects were placed in one of the following categories: *Below Normal* (<18.5), *Normal* (18.5-24.9), *Overweight* (25.0-29.9), or *Obese* (30.0-34.9).[9] Pulmonary function measurements were obtained with subjects seated in their wheelchairs using open-circuit spirometry equipment (model TrueOne 2400, Parvo Medics, Sandy, UT). A minimum of 3 trials were performed according to the recommendations of the American thoracic Society.[10] The values for forced vital capacity (FVC), forced expired volume in one second (FEV1), the ratio of FEV1/FVC, peak expiratory flow rate (PEFR), and maximum ventilator volume (MVV) were obtained and the best efforts for FVC, FEV1, and MVV were recorded. Spirometry results were reported as absolute values and compared to standards for tetraplegic individuals.[11]

Subjects were called once weekly at home to monitor drug compliance, health status, and possible adverse drug effects. Interval health history and physical exams were performed at each of the 5 clinic visits.

Statistical Analyses

Statistical analyses based on General Linear Model, non-parametric Friedman Rank ANOVA, and Estimated Marginal Means time were performed using SPSS program. Repeated measures methods were used to analyze within-subject variance associated with change in study variables from baseline to post-treatment

Results

All subjects had tetraplegia: 7 were American Spinal Injury Association (ASIA) neurological class A and 3 were ASIA class B (ref). The mean age was 32.5 years (range: 23-50) and the mean duration of injury was 8.8 years (range: 2-26).

Total body composition showed a small but significant mean percent increase in LBM of 1.9 ($p=0.018$) after 8 weeks of therapy and a small mean percent decrease in BF of -1.3 that did not reach significance ($p=0.09$). Although the average baseline value for LBM in the arms increased by 4.0 percent while on oxandrolone, the change was not significant ($p=0.22$). BF in the arms decreased slightly by -0.4 percent during the same interval (Table 1). Twelve weeks following the course of oxandrolone (study week 20), there was an additional mean percent increase over that observed at 8 weeks in LBM in the arms of 7.5 percent and in total body of 2.0 percent.

The mean BMI at baseline was 24 .9 (range: 14.4-32.7) and after 8 weeks of treatment with oxandrolone the BMI decreased slightly to an average of 24.7 while the range tightened to 16.0-31.2. Baseline BMIs were as follows: 2 subjects were in each of the *Below Normal* and *Overweight* categories and 3 were in each of the *Normal* and *Obese* categories. After intervention, the average BMI increased for *Below Normal* subjects by 12.8 % and decreased for the *Obese* group by 6.1%. There was no change in the *Normal* individuals and a small increase from baseline of 1.5% in the *Overweight* subjects (Table 2). None of the changes in BMI were significant.

Pulmonary function tests prior to taking oxandrolone were on average 82.6% of the values reported for other tertaplegics.[11] Mean percent changes following treatment increased for FVC, FEV1, and MVV (3.3, 2.6, and 9.3, respectively) and decreased by 3.4 for PEFR but these changes did not reach significance (Table 3).

Lipid profile and LFTs were normal in all subjects at baseline. These tests became abnormal or trended toward abnormal while on oxandrolone with the exception of triglycerides and albumin which changed on average less than 1%. The mean values for LDL-c and TC increased after treatment by 32.1 and 11.5%, respectively, and HDL-c declined on average -26.8%. There was an increase from baseline after 8 weeks of oxandrolone in the mean values for ALT (65.5%), AST (44.5%), and LDH (9.7%). Only the changes in LDL-c and HDL-c were significant ($p=0.013$, $p=0.017$, respectively). Changes in ALT, AST, and LDH were not significant. By week 20, or 12 weeks after completing the course of oxandrolone, all of the lipid tests and LFTs returned to baseline or the normal range.

Normal laboratory values for lipids and LFTs are: TC 100-200 mg/Dl, TG 10-149 mg/dL, LDL-c 0-99 mg/dL, HDL-c 40-85 mg/dL, ALT 13-51IU/L, AST 10-42 IU/L, LDH 313-618IU/L, and ALB 3.5-4.8 mg/dL.

Discussion

This group of healthy subjects with chronic tetraplegia had BMIs that ranged from 14.4 to 32.7. Because the BMI is an easy and quick number to calculate, it has become a valuable and widely used yardstick for classifying individuals with respect to obesity and related risk factors for morbidity and mortality. In 1988, the World Health Organization defined obesity as > 22% BF.[9] However, as this study and others have shown, the BMI has serious limitations when used to identify obesity in populations with SCI.[12] This is especially true with tetraplegics where the BMI classification can be quite misleading. For

example, the 5 subjects reported here who had BMIs in the *Below Normal* and *Normal* categories at baseline had a mean total body fat of 32.4% of their weight. This kind of finding results in what can be termed "Below normal or normal BMI obesity".

The shift in body composition is especially evident when compared to able-bodied controls. Table 4 summarizes data for regional and total body composition from our study, a second group of tetraplegics and a control population.[2] The subjects we studied had almost 1.5 times the percent BF and only 83 percent LBM when compared to these controls. Similar body composition abnormalities have been reported in other groups of tetraplegics, ranging from 25.5 to 35.0 % BF.[2, 13,14] The reason for this shift in body composition despite a “below normal” or "normal" BMI has been well documented. [15-18] Following SCI, muscle begins to atrophy and is replaced with fat which also accumulates around the abdominal viscera producing “central obesity”. In addition, there is compelling evidence that the DEXA scans used to determine body composition in both clinical and research settings underestimate the amount of fat present in individuals with SCI.[19] This disproportionate accumulation of fat in individuals with SCI has serious implications for long term morbidity and mortality.[12] In particular, there is a growing body of evidence that demonstrates the role of adipocytes in leading to the metabolic syndrome (defined as obesity plus 2 of the following conditions: dyslipidemia, hypertension, and insulin resistance).[12, 20]

Despite the presence of a large percent BF in our subjects, baseline lipids were normal. After treatment with oxandrolone, there were abnormal changes in the serum lipids as well as the LFTs. On average, the LDL-c increased by 32.1% and the HDL-c declined by -26.8%. Mean LFTs changes were greatest for AST which increased 44% and ALT which increased by 65.5%. Spungen et al.[8], in a group of 10 subjects with tetraplegia, reported a significant increase in ALT and a significant decrease in HDL-c after treatment with oxandrolone for 4 weeks. Other LFTs and serum lipids increased only slightly from baseline. Time for the abnormal values to return to normal was not described. In our series, abnormal serum lipids and LFTs returned to baseline or close to baseline in the normal range by 20 weeks. Whether long-term use of oxandrolone might result in more pronounced laboratory abnormalities or underlying pathologic tissue changes needs to be explored further if oxandrolone is to be used as a therapeutic agent in the clinical setting.

Although we did observe an increase in 3 of 4 PFTs, none of the changes were statistically significant. This is in contrast to the study by Spungen et al.[8] which found a significant improvement in FVC, FEV1, and forced inspiratory vital capacity (FIVC) in a group of 10 subjects with tetraplegia treated with oxandrolone 20mg/day for 1 month.

We conclude that treatment with the anabolic agent oxandrolone 20mg/day for 8 weeks can provide short-term positive effects in subjects with tetraplegia that are associated with modest improvement in PFTs and in arm and total body LBM. In addition, abnormal changes in serum lipids and LFTs during treatment with oxandrolone indicate that reported benefits of using anabolic steroid in the tetraplegic population must be carefully weighed against potential adverse effects, especially with long-term use.

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Tables

Table 1: Arm and Total Body Composition at Baseline and After 8 Weeks on Oxandrolone

	Baseline Mean+/-SD	**8 week Mean+/-SD**	% **Change**
		Total Body	
LBM (kg)	48.7+/-8.5	49.6+/-7.0	1.9*
BF (kg)	26.7+/-12.4	26.3+/-12.7	-1.3**
		Arms	
LBM (kg)	5.6+/-2.5	5.9+/-1.8	4.1**
BF (kg)	2.3+/-1.5	2.3+/-1.6	-0.4**

Abbreviations: LBM, Lean body mass; BF, Body fat.

*P<.02.
**Not statistically significant.

Table 2: BMI Classification at Baseline and Following Treatment with Oxandrolone*

BMI Category	N	Baseline Mean	Week 8 Mean	Mean % Chg
Below NL (<18.5)	2	14.9	16.8	12.8
Normal (18.5-24.9)	3	23.7	23.7	0
Overweight (25.0-29.9)	2	27.1	27.5	1.5
Obese (30.0-34.9)	3	31.2	29.3	-6.1

*BMI= Body Mass Index (kg/m^2)

Table 3: Pulmonary Function Results at Baseline and After 8 Weeks of Oxandrolone

	Baseline	8 Week	Mean % Chg
FVC (L)	2.75+/-0.90	2..84+/-0.84	3.3
FEV1 (L)	1.94+/-0.95	1.99+/-0.88	2.6
FEV1/FVC %	62.23	60.78	- 2.3
PEFR (L)	3.81+/-2.41	3.68+/-2.58	- '3.4
MVV (L)	82.19+/-23.60	89.82+/-29.17	9.3

Abbreviations: FVC, forced vital capacity; FEV1, forced expiratory volume in 1 second; PEFR, peak expiratory flow rate; MVV, maximum ventilatory volume.

Table 4: Comparison of Regional and Total Body Composition in Two Groups of Tetraplegics with Controls

	Tetras* (n=66)	Tetras** (n=10)	Controls* (n=100)
		Arms	
LBM (kg)	4.94	5.63	7.17
BF (kg)	3.16	2.34	1.63
		Total Body	
LBM (kg)	42.26	48.65	58.82
BF (kg)	24.11	26.67	18.74

Abbreviations: LBM, Lean body mass; BF, Body fat.
*Reference 2.
**This study.

Project D3: Development and Clinical Validation of a Children's Version of the Automated Neuropsychological Assessment Metrics (ANAM)

Abstracts for poster presentations for the D3 Project – Roebuck Spencer:

To be presented at the National Academy of Neuropsychology, October 2008

Initial Validation of a Pediatric Version of ANAM

Roebuck-Spencer, T.M., Kenealy, L., Gioia, G., & Bleiberg J.

Objective: The Automated Neuropsychological Assessment Metrics (ANAM) has been shown to be effective in tracking recovery of cognitive functioning following concussion and cognitive effects of medications. ANAM has been used down to age 13 but no standard version exists for children. The current study sought to develop and validate a pediatric version of ANAM (ped-ANAM).

Method: Ped-ANAM was modified so that test directions, format, and stimuli were appropriate for middle school age children. Subtests included in the battery were similar to the adult version and included measures of simple- and choice-reaction time, visual spatial discrimination, working memory, and learning and memory. Ped-ANAM was administered to a group of normally developing children between the ages of 10 and 12 (n=47). Children, recruited from the community, took ped-ANAM and a battery of neuropsychological tests. Parents completed behavioral questionnaires.

Results: Results indicated that children in this age group were able to understand and complete the battery with low failure rates, defined by accuracy rates < 60%. Children showed the greatest failure rates on a test of mental manipulation of spatial information. Few differences in test performance were seen between boys and girls and across age. Strong correlations were seen between ped-ANAM subtests and neuropsychological tests.

Conclusions: This study provides initial validation of ped-ANAM with normative reference data for 10-12 year olds. Results indicate that this test is appropriate for children within this age range. Future studies will examine the feasibility of using ped-ANAM with clinical samples and the ability of this battery to track cognitive change over time.

Presented in 2007 at the American College of Rheumatology Meeting:

Diagnosis Of Childhood-Onset Lupus Neurocognitive Impairment In A Clinical Setting: Usefulness Of Computer Based Testing And Self-Report

Author Block: Natasha M. Ruth[1], Tresa M. Roebuck-Spencer[2], T. Brent Graham[1], Thomas A. Griffin[1], Alexei A. Grom[1], Murray H. Passo[1], Douglas M. Ris[1], Hermine I. Brunner[1]. [1]Cincinnati Children's Hospital, Cincinnati, OH; [2]National Rehabilitation Hospital, Washington, DC

Purpose: 1) To determine the prevalence of neurocognitive involvement (NCI) in children with cSLE as measured by formal neurocognitive testing; 2) to assess the usefulness of the computer based pediatric Automated Neuropsychological Assessment Metrics (pANAM) and the Self Assessment Neuropsychiatric Questionnaire (NSAQ) for identifying children with NCI in a clinical setting.
Methods: A random sample of cSLE patients (n= 24) and age & gender matched controls (best-friends or JIA patients) were studied. For cSLE patients information on disease activity, damage, medication use, and the results of standard of care (SOC) laboratory testing were obtained. The NSAQ (46 items; yes/no answers) adapted from a previously published NCI self-report questionnaire, and the p-ANAM were completed by all subjects (duration 30- 45 min), while only those with cSLE underwent formal neurocognitive testing assessing various aspects of cognition (FNCT). NCI was defined as a z-score in 2 cognitive domains between -1.0 and -1.99 or $\leq$ -2.0 in 1 cognitive domain on FNCT.
Results: Forty percent (24/60) of all cSLE patients followed at the center were sampled (mean age:15; range:10-22 yrs, Caucasian:Non-Caucasian = 13 :11). NCI was present in 10 of 24 cSLE patients. The prevalence of NCI in cSLE was significantly higher than in normative populations (42% vs. 20.5%; p=.032). Compared to those without NCI, there was a trend towards a higher prevalence of renal disease and higher disease activity among cSLE pts with NCI (6/10 vs. 4/14), however none of the SOC tests including antiphospholipid and anti-dsDNA antibodies, medication, or global damage differed between the two groups. On many of the pANAM subtests, the “throughput score” (representing the product of speed and accuracy of task performance) was moderately correlated with the FNCT results (p<.05). Conversely, the NSAQ was neither sensitive nor specific for identifying pts with NCI. Several of the pANAM subtests were significantly different between cSLE patients and controls including: simple reaction time (p=.01), procedural reaction time (p=.01), logical reasoning symbolic (p=.07), memory search (p=.03).
Conclusions: There is a high prevalence of NCI among children with cSLE. The diagnosis of NCI in cSLE is difficult in the clinical setting suggesting that screening tools for NCI are required. Although self-assessment questionnaires are thought to be useful for adults with SLE, this appears not to be true for children. Similar to the ANAM developed for adults, the pANAM appears useful for detecting NCI in a clinical setting.

Presented in 2007 at the American College of Rheumatology Meeting:

The Pediatric Automated Neuropsychological Assessment Metrics (Ped-ANAM) in Childhood-onset Systemic Lupus Erythematosus (cSLE) - No Significant Practice Effect in First Three Trials

Deborah M. Levy, Tresa M. Roebuck-Spencer, Cynthia Aranow, Hermine I. Brunner.

Purpose: The Pediatric Automated Neuropsychological Assessment Metrics (Ped-ANAM; short version) is a computerized neuropsychological battery of tests used to assess neurocognitive function of children $\geq$ 10 years, requiring 15 to 25 min for completion. Preliminary study suggests that it can be used in childhood-onset Systemic Lupus Erythematosus (cSLE). Our objective was to assess for initial practice effects when the Ped-ANAM is administered to children and adolescents with cSLE.

Methods: Thirty-nine subjects with cSLE completed the Ped-ANAM three times during one study visit. Each test completion required approximately 15 to 25 minutes. All data was captured by software and a subject's neurocognitive function was based on Ped-ANAM performance parameters: mean (std dev) of time to correct response, accuracy, speed and throughput (accuracy multiplied by speed) for each subtest.

Results: No subject had ever completed the Ped-ANAM prior to their study visit. Subjects (M : F = 8 : 31) had a median age of 16.9 yrs (range 10.2 – 21.7 yrs) and a median disease duration of 3.2 yrs (range 0.3 to 12.4 yrs). This predominantly inner-city population was 62% (24/39) Hispanic, 15% (6/39) African-American, 8% (3/39) Asian, and 15% (6/39) Other (White or Mixed ethnicity). After accounting for multiple tests, Kruskal Wallis non-parametric Analysis of Variance suggested that there were no important absolute differences in the performance parameters between trials, other than for "Spatial Processing (SPD)" SPD-accuracy ($p=.0009$) and SPD-throughput score ($p<.0001$). The SPD subtest tests spatial analysis, requiring the subject to determine if two bar graphs, one presented upright and one rotated 90 degrees, are the same or different. Between trials one and three, performance on two subtests declined (p=NS), possibly an intereference effect from previous trials. Consistency of Ped-ANAM performance was further assessed by intraclass correlation scores (ICC). Performance parameters' ICC ranged between 0.58 and 0.95 (strong agreement) for all parameters except for those pertaining to the "Simple Reaction Time" subtest (ICCs: 0.38 - 0.46; moderate agreement).

Conclusions: cSLE subjects who newly completed the Ped-ANAM had a minimal initial practice effect. This supports the Ped-ANAM having high test-retest reliability, further improving its usefulness for the assessment of neuropsychological functioning of children and young adults with cSLE. Unlike the Adult version of the ANAM, there may be no learning effect of the Ped-ANAM in a population of young people with cSLE; other populations (non-diseased controls and younger subjects) must be tested.

The Pediatric Automated Neuropsychological Assessment Metrics (Ped-ANAM) in Childhood-onset Systemic Lupus Erythematosus (cSLE) - No Significant Practice Effect in First Three Trials

Deborah M. Levy[1], Tresa M. Roebuck-Spencer[2], Cynthia Aranow[3], Hermine I. Brunner[4].

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ABSTRACT

Purpose: The Pediatric Automated Neuropsychological Assessment Metrics (Ped-ANAM; short version) is a computerized neuropsychological battery of tests used to assess neurocognitive function of children ≥ 10 years, requiring 15 to 25 min for completion. Preliminary study suggests that it can be used in childhood-onset Systemic Lupus Erythematosus (cSLE). Our objective was to assess for initial practice effects when the Ped-ANAM is administered to children and adolescents with cSLE.

Methods: Thirty-nine subjects with cSLE completed the Ped-ANAM three times during one study visit. Each test completion required approximately 15 to 25 minutes. All data was captured by software and a subject's neurocognitive function was based on Ped-ANAM performance parameters: mean (std dev) of time to correct response, accuracy, speed and throughput (accuracy multiplied by speed) for each subtest.

Results: No subject had ever completed the Ped-ANAM prior to their study visit. Subjects (M : F = 8 : 31) had a median age of 16.9 yrs (range 10.2 – 21.7 yrs) and a median disease duration of 3.2 yrs (range 0.3 to 12.4 yrs). This predominantly inner-city population was 62% (24/39) Hispanic, 15% (6/39) African-American, 8% (3/39) Asian, and 15% (6/39) Other (White or Mixed ethnicity). After accounting for multiple tests, Kruskal Wallis non-parametric Analysis of Variance suggested that there were no important absolute differences in the performance parameters between trials, other than for "Spatial Processing (SPD)" SPD-accuracy (p=.0009) and SPD-throughput score (p<.0001). The SPD subtest tests spatial analysis, requiring the subject to determine if two bar graphs, one presented upright and one rotated 90 degrees, are the same or different. Between trials one and three, performance on two subtests declined (p=NS), possibly an intereference effect from previous trials. Consistency of Ped-ANAM performance was further assessed by intraclass correlation scores (ICC). Performance parameters' ICC ranged between 0.58 and 0.95 (strong agreement) for all parameters except for those pertaining to the "Simple Reaction Time" subtest (ICCs: 0.38 - 0.46; moderate agreement).

Conclusions: cSLE subjects who newly completed the Ped-ANAM had a minimal initial practice effect. This supports the Ped-ANAM having high test-retest reliability, further improving its usefulness for the assessment of neuropsychological functioning of children and young adults with cSLE. Unlike the Adult version of the ANAM, there may be no learning effect of the Ped-ANAM in a population of young people with cSLE; other populations (non-diseased controls and younger subjects) must be tested.

BACKGROUND

- **At present, there is no universally accepted method to determine cognitive dysfunction in patients with childhood-onset SLE (cSLE)**
- **Initial data suggests that the Pediatric version of the Automated Neuropsychological Assessment Metrics (Ped-ANAM) may be a valid tool to assess neurocognitive dysfunction in cSLE**
- **Traditional neuropsychological testing requires 3 or more hours of testing with a licensed psychologist; the Ped-ANAM can be completed in 15 – 25 minutes, and can be repeated frequently without a significant learning curve**
- **Researchers studying the adult version of the ANAM report an initial learning curve during the first three trials**

PURPOSE

- **To determine the presence of initial practice effects when the Ped-ANAM is repeatedly administered to children and adolescents with cSLE.**

METHODS

- **Patients with cSLE followed at the Morgan Stanley Children's Hospital of New York-Presbyterian were eligible to enroll in a longitudinal observational cohort of neurocognitive function**
- **49 cSLE patients completed the Ped-ANAM three times in a row during one study visit**
- **Subject's neurocognitive function was based on Ped-ANAM performance parameters: mean (std dev) of time to correct response, accuracy, speed and throughput (accuracy multiplied by speed) for each subtest**
- **Statistical analysis (using SAS) included linear mixed models for multiple observations with Tukey's post-hoc analysis to account for multiple tests. Intraclass Correlations (ICCs) were determined to ensure adequate test-retest reliability over multiple trials**

CUMC IRB #AAAB2133

ANAM Subtest	Description of Task
Code Substitution (CDS)	Decide if a symbol/digit pairing is consistent with pairings presented in a "code" above
Code Substitution Delayed (CDD)	Presented 15 – 20 minutes after CDS. Decide if a presented symbol/digit pairing is consistent with the earlier presented "code"
Matching to Sample (MSP)	Select which of two designs match a target design presented five seconds earlier
Mathematical Processing (MTH)	Decide whether the solution to a two step math problem (eg 3 + 2 = 5) is correct or incorrect
Procedural Reaction Time (PRO)	A stimulus is presented on the screen, (a 2, 3, 4, or 5), must hit left mouse button if a "2" or "3", right mouse button if a "4" or "5"
Sternberg Memory Test (STN)	Memorize a string of 6 letters and later determine whether individually presented letters were included in the original string
Spatial Processing (SPD)	Examine two bar graphs, one presented upright and one rotated 90 degrees, then decide if the two bar graphs are the same are different.
Simple Reaction Time (SRT)	Measures simple reaction time in response to a stimulus (*)

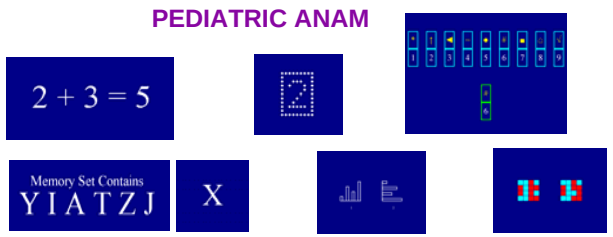
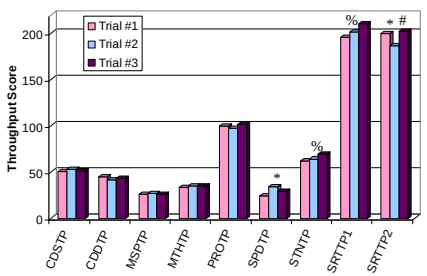


Figure 1: Examples of stimuli presented in PedANAM and explanation of Subtests

ABBREVIATIONS
SRT – Simple Reaction Time
PRO – Procedural Reaction Time
CDS – Code Substitution
CDD – Code Substitution Delayed
MSP – Matching to Sample
SPD – Spatial Processing
STN – Sternberg Memory Search
MTH – Mathematical Processing



LEGEND
Significant differences (p<.05) between trials:
*** trials 1&2**
% trials 1&3
 # trials 2&3

RESULTS

	cSLE Subjects N= 49
Gender	**13 Male (27%)** **36 Female (73%)**
Age in years (median, range)	**16.0 (10.2 – 21.7)**
Disease Duration in years (median, range)	**3.1 (0.3 – 12.4)**
Ethnicity	
Hispanic	**31 (63%)**
African-American	**7 (14%)**
Caucasian	**5 (10%)**
Asian	**5 (10%)**
Other (mixed race/ethnicity)	**1 (2%)**

Table 1: Demographics

	CDSTP	CDDTP	MSPTP	MTHTP	PROTP	SPDTP	STNTP	SRTTP1	SRTTP2
ICC	0.755	0.672	0.817	0.896	0.736	0.551	0.698	0.642	0.650

Table 2: Intraclass Correlations for Throughput scores for Trials 1- 3

All ICCs indicated Strong Agreement between trials, indicating consistent effort (test-retest reliability) by study participants (ICC > 0.50 = "Strong Agreement")

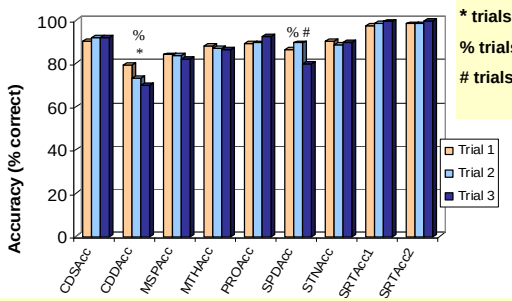


Figure 2: Ped-ANAM Subtest Results over Trials 1 – 3 Using Mixed Models

Significant differences of Accuracy and Throughput scores between trials are indicated (p<.05 after Tukey's post-hoc correction). Symbols defined in legend above.

CONCLUSIONS

- **A minimal learning effect was observed overall, except for the Code Substitution Delayed subtest – this learning effect may wane if more time is introduced between testing sessions**
- **There was a high test-retest reliability between trials, with Intra-class Correlations (ICCs) > 0.5 for throughput scores of all PedANAM subtests**
- **Together with previous published research this suggests that the PedANAM may be a suitable ad-hoc screening tool for neurocongitive functioning**
- **Longer-term learning effects and responsiveness to change require further evaluation**

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ORIGINAL ARTICLE

Initial Validation of the Pediatric Automated Neuropsychological Assessment Metrics for Childhood-Onset Systemic Lupus Erythematosus

HERMINE I. BRUNNER,[1] NATASHA M. RUTH,[1] APRIL GERMAN,[1] SHANNEN NELSON,[1] MURRAY H. PASSO,[1] TRESA ROEBUCK-SPENCER,[2] JUN YING,[3] AND DOUGLAS RIS[1]

Objective. **To evaluate the concurrent validity and diagnostic accuracy of the pediatric Automated Neuropsychological Assessment Metrics (Ped-ANAM) when used in childhood-onset systemic lupus erythematosus (SLE).**

Methods. **Formal neuropsychological testing and the Ped-ANAM were performed on 27 children with SLE who had not been previously diagnosed with neuropsychiatric SLE. Performance when completing the 10 Ped-ANAM tests was based on accuracy (AC), mean time to correct response, coefficient of variation of the time required for a correct response (CVc), and throughput. Formal neuropsychological testing was used as a criterion standard for diagnosing neurocognitive dysfunction (NCD; yes/no).**

Results. **NCD was common and present in 16 (59%) of 27 participants. Ped-ANAM performance parameters were often moderately correlated with the Z scores on formal neuropsychological testing. The NCD group differed significantly ($P < 0.05$) from the normal cognition group in 3 Ped-ANAM tests: CVc with mathematical processing (MTH-CVc), AC with continuous performance test (CPT-AC), and CVc with spatial processing (SPD-CVc). Areas under the receiver operating curves (AUCs) ranged between 0.75 and 0.84 when each of these parameters (CPT-AC, MTH-CVc, SPD-CVc) was used to identify NCD independently. The AUC was improved to 0.96 for the combined assessment.**

Conclusion. **The Ped-ANAM has concurrent validity when used in children with SLE. Initial validation suggests that the Ped-ANAM could be a useful screening tool for NCD in children with SLE.**

KEY WORDS. Cognitive functioning; Systemic lupus erythematosus; Children; Automated Neuropsychological Assessment Metrics.

INTRODUCTION

Both children and adults with systemic lupus erythematosus (SLE) frequently report cognitive problems, and many studies have documented significant cognitive deficits with traditional neuropsychological test batteries (1,2). Most studies find cognitive deficits on tests measuring attention/concentration, cognitive flexibility, free-recall memory, and speed of information processing, suggesting the presence of a subcortical cognitive syndrome (3). Signs of neurocognitive dysfunction (NCD) in persons with SLE are often subtle and difficult to ascertain in daily clinical practice. Nonetheless, NCD has detrimental effects on patient quality of life (4), and thus constitutes an important disease feature.

The diagnosis of NCD with SLE is made by standardized neuropsychological testing (1). However, formal neuropsychological testing is costly, time intensive, and not readily accessible in daily clinical practice. Therefore, computer-administered performance applications to test cognition have been explored in recent years, apparently offering a promising approach to evaluating cognitive function in patients with various diseases (3,5–8). One of these applications is the Automated Neuropsychological Assessment Metrics (ANAM), designed as a clinical subset of a library of automated neurocognitive and performance tasks that

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provides a means of assessing cognitive functioning serially over repeated administrations (9). The ANAM has been found to be suitable for testing the cognitive abilities of adults with SLE and requires no prior knowledge about the use of computers (3,10). The usefulness of the recently developed pediatric version of the ANAM (Ped-ANAM) (11) for testing the cognition of patients with childhood-onset SLE has not been investigated and was the focus of our study. The study objectives were to investigate the concurrent validity of the Ped-ANAM and to assess the usefulness of the measure to screen for NCD in childhood-onset SLE.

PATIENTS AND METHODS

Patients. With approval of the institutional review board of a tertiary care center, we recruited patients diagnosed with SLE (12) prior to the age of 16 years from the pediatric rheumatology clinic. To be included in the study, participants had to lack a diagnosis of a preexisting disease that might negatively affect cognition other than SLE, including, but not limited to, attention deficit disorder, chronic headaches, and developmental delay. The latter was defined as placement in a special education classroom or a prior diagnosis of a learning disability by a health care professional.

Study procedures. The medical records of the participants were reviewed for the following information: age at the time of the study, race, sex, disease duration, medication use at the time of the study, and ever positive for antiphospholipid antibodies or lupus anticoagulant; disease activity was measured by the Systemic Lupus Erythematosus Disease Activity Index (13,14), and disease damage by the Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index (15,16). We also recorded whether there was a history of neuropsychiatric SLE as diagnosed by the treating pediatric rheumatologist or by formal neuropsychological testing.

Measures. *Pediatric Automated Neuropsychological Assessment Metrics.* The Ped-ANAM was recently designed for use in children ≥10 years of age (11). Although the traditional ANAM has been used in individuals as young as 13 years, it is primarily intended for older adolescents and adults because for some of the ANAM tasks, the reading level and stimuli presented are considered too complex for younger children. Therefore, the Ped-ANAM was adapted from the traditional ANAM to allow for the testing of younger individuals. Because many of the tasks in the Ped-ANAM are almost identical to the traditional ANAM, the Ped-ANAM can also be administered to older children, adolescents, or even adults. The strength of the Ped-ANAM is that it can be used for testing cohorts that encompass a wide range of ages, or cohorts with participants that cross traditional age categories, e.g., childhood, adolescence, and adulthood. The administration of the Ped-ANAM requires 30–40 minutes. Like the ANAM, the Ped-ANAM was designed for repeated testing (9).

The Ped-ANAM system is a library of tests and batteries designed for a broad spectrum of clinical and research applications (6,17) (Table 1) for assessing sustained concentration and attention, mental flexibility, spatial processing, cognitive-processing efficiency, arousal/fatigue level, learning, recall, and working memory. Some measures used in the Ped-ANAM are based on traditional cognitive tasks and in some cases are similar to familiar neuropsychological tests. Nevertheless, differences in implementation may affect what the test measures. For example, the Ped-ANAM simplifies the patient-computer interface by limiting patients' responses to 1 of 2 mouse buttons. Therefore, modifying tasks to permit binary responses (e.g., yes/no, same/different, greater than/less than) may modify the cognitive demands of the tasks and produce differences in tasks that otherwise might appear similar. Other Ped-ANAM tests are unique and not modeled based on traditional paper and pencil tests. Therefore, concurrent validity studies are crucial to help define the nature of the automated tests and to assist in their interpretation.

Since Ped-ANAM tasks are automated, they also produce scores capturing response time and performance efficiency. Patient efficiency in completing a specific test is reflected in the accuracy (AC), e.g., the percentage of correctly answered questions on the test, whereas the speed of completion is represented by the mean reaction time required to present a correct answer (MNc). The test's throughput (TP) score synthesizes the information on patient efficiency and speed in one single parameter ($TP = AC / MNc \times 60$). We also calculated the coefficient of variation of the time required to a correct response (CVc; standard deviation of reaction time to present a correct response divided by MNc) in an attempt to measure within-patient consistency when performing a specific Ped-ANAM test.

Formal neuropsychological testing battery. Standardized neuropsychological testing by a trained psychometrician was performed within 10 days of completing the Ped-ANAM. In the absence of a generally accepted neuropsychological battery for the assessment of neurocognitive functioning in children with SLE and based on the published literature of adults with SLE, we used a neuropsychological battery to measure various cognitive domains: memory, psychomotor speed, visuoconstructional processing, attention, and executive functioning. The specific standardized tests administered by a trained psychometrician were as follows: memory: Stories Subtest of the Children's Memory Scale, Immediate and Delayed Recall Trials (18) (for participants age ≥17 years: Logical Memory Subtest of the Wechsler Memory Scale III, Immediate and Delayed Recall Trials [19]), and Rey Osterrieth Complex Figure (ROCF), Immediate Recall and Delayed Recall Trials (20,21); psychomotor speed: Trail Making Test Part A (22), and Color naming, Color reading Subtests of the Delis Kaplan Executive Function System (23); visuoconstructional processing: Copy Trial of the ROCF (20,21); and attention/executive functioning: Trail Making Test Part B (22), and Color/Word Inhibition, Inhibition/Substitution of the Delis Kaplan Executive Functioning System (23).

Table 1. Automated Neuropsychological Assessment Metrics pediatric battery (Ped-ANAM)

Ped-ANAM subtest*	Abbreviation	Subtest description
1. Simple reaction time	SRT	20-item measure of reaction time. The test presents a simple stimulus on the screen (*) and the participant is required to press the left mouse key as quickly as possible following the presentation of the stimulus. This test is repeated at the end of the battery to assess both within-session reliability and the effect of fatigue on SRT performance.
2. Procedural reaction time	PRO	20-item measure of choice reaction time. The test presents a stimulus on the screen, a 2, 3, 4, or 5. The participant is required to press the blue (left) mouse key if a 2 or 3 is presented or the red (right) mouse key if a 4 or 5 is displayed.
3. Code substitution and code substitution delayed	CDS and CDD	The learning portion of this test assesses attention, concentration, and learning. In this test, a key containing a string of 9 symbols and 9 digits is displayed across the upper portion of the screen. Symbols and numbers are paired with a unique number located below a specific symbol. During the task, a "test" pair (i.e., a symbol and digit) is presented at the bottom of the screen, below the key containing the correct symbol number pairs. The objective is to indicate if the "test" pair matches the associated pair in the key at the top of the screen. The subject is instructed to try to remember the symbol-number pairs as they will be asked to recall them later. The delayed recall portion of this test is an explicit recognition memory task administered later in the test battery. For this subtest, the subject is presented only with a "test" pair and asked to remember whether the this symbol/number pairing is correct based on the earlier presented key.
4. Logical reasoning	LRS	This test consists of a practice and a real test in which the subject must decide if sentences presented on the screen make sense or not. Responses consist of pressing the blue (left) button if the sentence makes sense and the red (right) button if the sentence does not.
5. Spatial processing	SPD	Spatial processing is a test of spatial analysis and requires subjects to examine 2 bar graphs, one presented upright and one rotated 90°. They are then asked to decide if the 2 bar graphs are the same or different.
6. Continuous performance test	CPT	This is a test of sustained attention and working memory. Participants are asked to monitor a randomized sequence of numbers, 1–9. The numbers are presented one at a time in the center of the screen. Participants are asked to press a response button indicating whether or not the number presented on the screen matches the number that immediately preceded it. The subject is instructed to press the blue (left) mouse button if the number matches the previous stimuli or the red (right) button if the number does not match the previous stimuli.
7. Mathematical processing	MTH	Mathematical processing is a test of arithmetic, attention, and processing speed. The subject is required to decide if a math problem presented on the screen is correct or incorrect. Each problem includes one mathematical operation (addition or subtraction) on single-digit numbers. The subject is instructed to indicate if the problem is correct by pressing the blue (left) button or if the problem is incorrect by pressing the red (right) button.
8. Matching grids	MTG	Matching grids is a test of visuospatial discrimination. Two 4 × 4 grids are displayed side by side on the screen. The subject must then decide if the grids are exactly the same or different. The subject presses the blue (left) button if the grids are the same and the red (right) button if the grids are different.
9. Matching to sample	MSP	Matching to sample is a test of short-term memory, attention, and visuospatial discrimination. The subject is presented with a single design to study and remember. The design then disappears and the screen goes blank. Following a brief delay, 2 more designs appear on the screen. The subject must then decide which of the 2 designs matches the original. The subject presses the blue (left) button if the left comparison grid matches the original and the red (right) button if the right comparison grid matches the sample grid.
10. Sternberg memory search	STN	This is a test of sustained attention and working memory. Participants are presented with a set of 6 letters called the memory set ("secret code" in the pediatric version). They are allowed as long as they need to memorize the letters. Upon beginning the test, the code is removed from the screen and single letters begin appearing one at a time on the screen. The subject must then decide if the letter on the screen was contained in the secret code. The subject is instructed to press the blue (left) mouse button if the letter matches any of the letters in the secret code or the red (right) button if the letter does not match the code.

* All tests with the exception of CDD and the second version of SRT are preceded by a practice session that provides feedback to enhance learning.

Criterion standard: definition of neurocognitive dysfunction. Under consideration of patient age, published norms were used to score the participants' performance on each of the formal neuropsychological tests with results being expressed as Z scores (a Z score [SD] of 0 [1] corresponds to the mean ± SD scores of a normal healthy population). The Z scores of the tests included in the formal neuropsychological battery that assessed a given cognitive domain (memory, psychomotor speed, visuoconstructional processing, attention/executive functioning) were averaged. Participants with at least 2 average Z scores between −2 and −1 were considered to have NCD. Similarly, children with at least 1 average domain Z score of −2 or lower were classified to have NCD. All other participants were classified to have normal cognition, e.g., no NCD.

Statistical analysis. Demographic and clinical characteristics were summarized by median (range) for numerical variables and frequency (in percentage) for categorical variables. Nonparametric Wilcoxon's rank sum tests and Pearson's chi-square tests were used to compare medians and frequencies between SLE patients with and without NCD. All neuropsychological test scores (Z scores) and the Ped-ANAM test parameters (AC, MNc, CVc, and TP) were summarized by both median (range) and mean ± SEM. Given the relatively small number of participants included in this study, we used both parametric and nonparametric models to compare means and medians between the 2 NCD groups, e.g., participants with or without NCD. In particular, we used parametric analysis of covariance models to compare means after adjusting for demographic differences (age, race) between the 2 NCD groups, and nonparametric Wilcoxon's rank sum tests to compare medians (no adjustment). For each formal neuropsychological test score (Z score) separately, the relationship to the Ped-ANAM test parameters (AC, MNc, CVc, TP) was assessed using partial Pearson's correlation coefficients and Spearman's correlation coefficients, after adjusting for differences in age. To support sufficient concurrent validity, we expected that there was a larger than expected number of significant correlation coefficients ($P < 0.05$) between the Ped-ANAM parameters and the Z scores on formal testing (10).

The odds of NCD were predicted in multivariate logistic regression models, using each Ped-ANAM test parameter as a predictor and adjusting for demographic characteristics (age and race). Ped-ANAM test parameters that showed a significant difference between NCD groups and were significant predictors of odds of NCD were further assessed for their diagnostic accuracy using receiver operating characteristic (ROC) curves (24). An overall sensitivity (or specificity) given all possible specificities (or sensitivities) was evaluated using area under the ROC curve (AUC) analysis. The AUC (range 0–1) considers both the sensitivity and specificity of a diagnostic test over the range of possible values. Tests with AUC values ≤0.5 are not suited for diagnosing NCD (25). The overall sensitivity (specificity) is considered almost perfect, good/substantial, and fair/moderate if the AUC is 0.9–1.0, 0.70–0.89, and 0.51–0.69, respectively (24,26).

The diagnostic accuracy of the Ped-ANAM for NCD (present/absent) was assessed for the best parameter cutoff values (based on ROC analysis) of a given Ped-ANAM parameter and expressed as sensitivity/specificity for NCD. Finally, the accuracy of combinations of Ped-ANAM parameters was determined by classification and regression tree (CART) analysis (27). Using CART analysis, a diagnostic score was developed.

P values less than 0.05 were considered statistically significant. If *P* values from parametric and nonparametric models did not agree in the same comparison, a more conservative (or a larger) *P* value was preferred. Analyses were performed using SAS software, version 9.1 (SAS Institute, Cary, NC). The CART analysis was performed using SYSTAT software, version 11.0 (Systat, Point Richmond, CA). ROC curves were plotted using Splus software, version 6.2 (Insightful, Durham, NC).

RESULTS

Study participants and formal neuropsychological testing. English was the first language for all 27 study participants. The median age at the time of the study was 16.5 years (mean ± SD 15.6 ± 3.6, range 10–21). Most participants were female (n = 26), 13 patients (48%) were white, and none of the participants was Hispanic. None of the patients had problems understanding the Ped-ANAM instructions provided. Based on the results of the formal neuropsychological testing, 16 (59%) of 27 participants were considered to have NCD. Participants without NCD were more often white than those with NCD (64% versus 38%; *P* = not significant [NS]). Participants without NCD were also somewhat older than those with NCD (median [range] age 17 years [13–21] versus 13 years [10–20]; *P* = NS). Additionally, the median disease duration was 4 years (range 1–6) for patients without NCD and 2 years (range 1–6) for patients with NCD (*P* = NS). Compared with participants with NCD, there was a trend toward a lower prevalence of renal disease among participants without NCD (56% versus 33%; *P* = NS), whereas the 2 groups of patients were similar in disease activity, damage, presence of anti–double-stranded DNA antibodies, history of antiphospholipid antibodies, and mean dose of daily prednisone. Differences in performance on formal neuropsychological testing per NCD group are summarized in Table 2. Significant differences between NCD groups were only noted for the ROCF copy trial ($P < 0.01$) and the ROCF immediate recall trial ($P < 0.05$).

Concurrent validity analysis. We expected that participants with NCD would show inferior performance parameters when completing the Ped-ANAM as compared with those without NCD. Irrespective of performance parameter (AC, MNc, CVc, TP), there was a general trend toward participants with NCD performing worse as compared with those without NCD. However, the differences between NCD groups only reached significance for mathe-

Table 2. Formal neuropsychological testing Z scores*

Formal neuropsychological battery subtests	Participants with neurocognitive impairment (n = 16)		Participants without neurocognitive impairment (n = 11)	
	Mean ± SEM	Median (min, max)	Mean ± SEM	Median (min, max)
CMS-I	−0.23 ± 0.29	−0.17 (−2.67, 2.00)	0 ± 0.28	0.17 (−2.00, 1.33)
CMS-D	0 ± 0.28	−0.33 (−2.00, 2.33)	0.17 ± 0.26	0.33 (−1.33, 1.67)
ROCF-C	−1.59 ± 0.35†	−2.00 (−2.50, 1.50)‡	0.63 ± 0.25	1.00 (−1.50, 1.00)
ROCF-I	−1.08 ± 0.28§	−0.80 (−3.50, 0.60)¶	−0.19 ± 0.19	−0.20 (−1.10, 0.90)
ROCF-D	−0.99 ± 0.24	−0.90 (−3.50, 0.40)	−0.43 ± 0.23	−0.40 (−1.50, 0.70)
Trail-A	−1.05 ± 0.60	−0.30 (−5.09, 1.87)	0.01 ± 0.42	0.30 (−3.40, 2.60)
Trail-B	−1.17 ± 2.54	−0.16 (−6.00, 2.09)	0.17 ± 0.20	0.15 (−0.80, 1.30)
CW-I	0.16 ± 0.22	0.33 (−1.67, 1.33)	0.33 ± 0.22	0.67 (−1.0, 1.33)
CW-IS	−0.10 ± 0.21	0.00 (−2.00, 1.33)	0.28 ± 0.30	0.50 (−1.67, 1.67)
CW-CN	0.42 ± 0.24	0.33 (−1.00, 2.67)	0.33 ± 0.21	0.33 (−1.33, 1.33)
CW-R	0.36 ± 0.15	0.50 (−0.67, 1.67)	0.47 ± 0.18	0.33 (−0.33, 1.33)

* CMS-I = Stories Subtest of the Children's Memory Scale, Immediate Recall Trials; CMS-D = Stories Subtest of the Children's Memory Scale, Delayed Recall Trials; ROCF-C = Rey Osterrieth Complex Figure, copy trial; ROCF-I = Rey Osterrieth Complex Figure, immediate recall trial; ROCF-D = Rey Osterrieth Complex Figure, delayed recall trial; Trail-A = Trail Making Test Part A; Trail-B = Trail Making Test Part B; CW-I = Delis Kaplan Executive Functioning System, Color-Word—interference subtest; CW-IS = Delis Kaplan Executive Functioning System, Color-Word—interference/substitution subtest; CW-CN = Delis Kaplan Executive Functioning System, Color-Word—color naming subtest; CW-R = Delis Kaplan Executive Functioning System, Color-Word—color reading subtest.
† Significant difference of means between impaired and nonimpaired groups with $P < 0.01$ using parametric analysis of covariance (ANCOVA) models adjusted for age, sex, and race.
‡ Significant difference of means between impaired and nonimpaired groups with $P < 0.01$ using nonparametric Wilcoxon's rank sum tests.
§ Significant difference of means between impaired and nonimpaired groups with $P < 0.05$ using parametric ANCOVA models adjusted for age, sex, and race.
¶ Significant difference of means between impaired and nonimpaired groups with $P < 0.05$ using nonparametric Wilcoxon's rank sum tests.

matical processing (MTH), spatial processing (SPD), and the continuous performance tests (CPT) (Table 3).

Both Spearman's and Pearson's correlation coefficients were calculated, with Spearman's coefficients often supporting a closer relationship between Ped-ANAM tests and the formal neuropsychological battery. Significant correlations often persisted, irrespective of the analytic approach chosen and the Ped-ANAM parameter considered. Only Pearson's correlation coefficients are shown in Table 4, providing a conservative estimate of the relationship between formal testing and the Ped-ANAM parameters. We found 92 correlations that were significantly associated ($P < 0.5$) with the formal Z scores of the neuropsychological battery. Based on the number of correlations calculated (n = 392), we would expect ~17.7 significant correlations by chance alone using a P value of 0.05, supporting the concurrent validity of the Ped-ANAM (10). For reasons not well understood, the formal neuropsychological tests most closely correlated with Ped-ANAM parameters did not discriminate well between participants with versus those without NCD.

Predictive analysis. To identify Ped-ANAM tests that are especially suitable to identify NCD in childhood-onset SLE, we calculated odds ratios using multivariate logistic models (outcome: NCD yes/no) that adjusted for age differences between groups. Our results suggested that the CVc with MTH and SPD (MTH-CVc and SPD-CVc, respectively) and the AC with CPT (CPT-AC) were significant predictors of NCD. Specifically, the odds of having NCD increased by 21% or 18% in response to every 1% increase of MTH-CVc or SPD-CVc, respectively. Conversely, the odds of NCD decreased by 22% as a result of a 1% increase of CPT-AC.

Diagnostic accuracy analysis. The above-mentioned Ped-ANAM test parameters (CPT-AC, MTH-CVc, SPD-CVc) were further assessed for their diagnostic accuracy of NCD. The ROC curves of CPT-AC, MTH-CVc, and SPD-CVc when used individually are shown in Figures 1A, 1B, and 1C, respectively. The AUC was 0.84 for CPT-AC, 0.75 for MTH-CVc, and 0.79 for SPD-CVc, indicating good to substantial accuracy.

Based on CART analysis, cutoff values for CPT-AC, MTH-CVc, and SPD-CVc were determined to be at 88.75%, 24.04%, and 38.92%, respectively. For CPT-AC ≤88.75%, the corresponding sensitivity and specificity for the presence of NCD were 62.5% and 100%, respectively; for MTH-CVc >24.04%, the sensitivity and specificity were 87.5%/60%, respectively; and for SPD-CVc >38.92%, the sensitivity and specificity were 37.5%/100%, respectively. Thus, none of the 3 Ped-ANAM parameters by themselves had high sensitivity and concomitantly high specificity, leading us to explore the diagnostic value of combinations of Ped-ANAM parameters using CART analysis. A diagnostic score (range 1–4) was developed using CART analysis, with a lower (higher) score indicating higher (lower) likelihood of NCD (score = 1 if CPT-AC ≤88.75%; score = 2 if CPT-AC >88.75% but MTH-CVc >24.04% and SPD-CVc >39.82%; score = 3 if CPT-AC >88.75% and MTH-CVc >24.04% but SPD-CVc ≤39.82%; and score = 4 if both CPT-AC >88.75% and MTH-CVc ≤24.04%). As noted above, a cutoff at score 1 had 62.5% sensitivity and 100% specificity for NCD, whereas a cutoff at score 2 had

Table 3. Automated Neuropsychological Assessment Metrics pediatric battery (Ped-ANAM) subtest performance*

Parameter/ test	Participants with neurocognitive impairment (n = 16)		Participants without neurocognitive impairment (n = 11)	
	Mean ± SEM	Median (min, max)	Mean ± SEM	Median (min, max)
CVc (%)				
CDD	50.40 ± 8.20	39.42 (20.22, 135.66)	51.11 ± 11.54	40.69 (27.11, 148.51)
CDS	32.99 ± 2.17	32.03 (21.07, 50.69)	31.29 ± 2.39	29.66 (18.83, 45.68)
CPT	27.10 ± 1.95	25.25 (13.87, 46.66)	24.78 ± 1.65	25.09 (13.05, 33.92)
LRS	28.25 ± 2.38	23.84 (17.45, 48.11)	22.43 ± 1.26	22.60 (15.22, 27.54)
MSP	44.57 ± 3.44	43.42 (27.54, 77.59)	47.72 ± 4.98	44.73 (32.92, 87.27)
MTG	27.59 ± 2.39	25.31 (16.14, 50.25)	25.04 ± 2.09	25.04 (14.49, 34.73)
MTH	31.46 ± 1.97†	30.98 (20.72, 45.40)‡	24.78 ± 2.23	22.33 (15.98, 38.82)
PRO	22.55 ± 1.66	21.04 (12.46, 34.41)	17.81 ± 0.89	18.09 (14.60, 22.53)
SPD	39.05 ± 2.01†	38.017 (28.51, 53.42)‡	30.31 ± 2.29	30.01 (18.43, 42.52)
STN	32.69 ± 3.72	30.65 (14.38, 70.05)	31.99 ± 5.39	23.77 (13.69, 63.84)
SRT1	25.53 ± 2.93	24.30 (7.54, 54.51)	20.23 ± 3.27	19.46 (7.72, 36.43)
SRT2	34.42 ± 6.93	27.84 (8.98, 113.52)	20.68 ± 3.56	18.54 (10.26, 46.16)
AC (%)				
CDD	87.39 ± 2.87	88.89 (55.56, 100.00)	80.86 ± 6.83	91.67 (36.67, 100.00)
CDS	96.01 ± 0.66	95.83 (91.67, 100.00)	92.92 ± 4.38	98.61 (50.00, 100.00)
CPT	81.17 ± 3.75†	87.50 (46.25, 97.50)‡	94.09 ± 1.14	93.75 (88.75, 100.00)
LRS	97.19 ± 0.91	100.00 (90.00, 100.00)	98.18 ± 1.01	100.00 (90.00, 100.00)
MSP	88.89 ± 3.09	91.16 (50.00, 100.00)	85.00 ± 4.72	90.00 (40.00, 95.00)
MTG	94.37 ± 1.57	95.00 (80.00, 100.00)	95.00 ± 1.65	95.00 (85.00, 100.00)
MTH	90.93 ± 2.47†	95.00 (70.00, 100.00)§	99.09 ± 0.91	100.00 (90.00, 100/00)
PRO	91.56 ± 3.58	95.00 (40.00, 100.00)	96.36 ± 1.36	100.00 (90.00, 100.00)
SPD	88.75 ± 1.61	90.00 (70.00, 95.00)	90.90 ± 1.31	90.00 (85.00, 95.00)
STN	93.33 ± 1.66	93.33 (76.67, 100.00)	95.45 ± 2.21	96.67 (76.67, 100.00)

* Performance parameters MNc (mean reaction time required to present a correct answer) and TP (throughput) are not presented because all the means are insignificant between the 2 groups of participants. CVc = coefficient of variation of time to correct response; AC = accuracy; see Table 1 for additional definitions.
† Significant difference of means between impaired and nonimpaired groups with $P < 0.05$ using parametric analysis of covariance (ANCOVA) models adjusted for age, sex, and race.
‡ Significant difference of means between impaired and nonimpaired groups with $P < 0.05$ using nonparametric Wilcoxon's rank sum tests.
§ Significant difference of means between impaired and nonimpaired groups with $P < 0.01$ using nonparametric Wilcoxon's rank sum tests.

a sensitivity of 81.25% and a specificity of 100% for NCD in the study population. A cutoff of score 3 had 100% sensitivity and 60% specificity, and a cutoff of score 4 had a sensitivity and specificity of 100% and 40%, respectively. Taken together, the AUC for NCD when using this CART score was 0.96.

DISCUSSION

We studied the usefulness of the Ped-ANAM in diagnosing NCD in childhood-onset SLE. The results of this study suggest that this computer-administered performance test is feasible, has concurrent validity, and appears to be a promising screening tool for NCD.

Neuropsychiatric SLE is thought to be more common in children as compared with adults, with up to 95% of children manifesting at least 1 symptom of neuropsychiatric SLE and NCD being present in up to 55% (2,28). NCD may be transitory (29) or persistent over years (30) and can occur in patients without clinical disease activity (31,32). Because symptoms are often subtle, the identification of NCD is sometimes difficult, requiring formal neuropsychological testing for its diagnosis. In an effort to allow efficient screening for NCD in a clinical setting, we explored the usefulness Ped-ANAM (11). Similar to previous studies in adults with SLE using the ANAM, a large number of the Ped-ANAM parameters were correlated with patient performance in formal testing (3,10), supporting the concurrent validity of the Ped-ANAM. Several Ped-ANAM parameters appeared especially suitable for discriminating groups of participants with versus without NCD from each other.

The ANAM has been used to demonstrate cognitive difficulties in numerous clinical populations, and increased reaction time is the most common finding (10,33). In this study, the MNc and TP values of the NCD group did not significantly differ from those of the normal cognition group. Rather, there was lower accuracy (AC) and higher within-patient variability in the time required to produce a correct response (CVc) with NCD. These results suggest that accuracy and consistency were more affected in this sample than speed of processing. Whether this finding is sample specific should be confirmed in future studies. Nonetheless, AC values were generally high, even with NCD. High AC values of Ped-ANAM tests are intended by the developers of the metrics to ensure that most individuals can complete the Ped-ANAM successfully (feasibility). However, given the pronounced negative skewness of the AC values for all Ped-ANAM tests and the fact that AC values changed with NCD, it is likely that the ability to

Table 4. Comparison of Automated Neuropsychological Assessment Metrics pediatric battery (Ped-ANAM) performance parameter and formal neuropsychological tests*

Ped-ANAM parameter	Formal neuropsychological battery†										
	CMS-I	CMS-D	ROCF-I	ROCF-D	ROCF-C	Trail-A	Trail-B	CW-I	CW-IS	CW-CN	CW-R
MNc											
CDD	−0.52‡	−0.49§	−0.24	−0.18	−0.19	−0.32	−0.31	−0.48§	−0.40	0.12	0.06
CDS	−0.46§	−0.50§	−0.41§	−0.34	0.06	−0.51§	−0.42§	−0.57‡	−0.43§	−0.48§	−0.52‡
CPT	−0.25	−0.33	−0.30	−0.16	0.06	−0.24	−0.08	−0.54‡	−0.44§	−0.46§	−0.43§
LRS	−0.61‡	−0.56‡	−0.35	−0.25	−0.41§	−0.14	−0.08	−0.53‡	−0.42§	−0.43§	−0.39
MSP	−0.23	−0.19	0.25	0.19	0.24	−0.07	0.00	−0.23	0.20	−0.37	−0.08
MTG	−0.40	−0.41§	−0.22	−0.06	−0.15	−0.06	0.03	−0.30	−0.08	−0.28	−0.11
MTH	−0.57‡	−0.61‡	−0.26	−0.18	−0.26	−0.32	−0.24	−0.39	−0.43§	−0.39	−0.20
PRO	−0.38	−0.41§	−0.26	−0.16	0.13	−0.42§	−0.41§	−0.42§	−0.49§	−0.41§	−0.41§
SPD	−0.24	−0.21	−0.07	−0.06	0.08	−0.37	−0.22	−0.27	−0.06	−0.30	−0.21
STN	−0.34	−0.45§	−0.19	−0.15	0.07	−0.17	0.01	−0.31	−0.25	−0.49§	−0.24
CVc											
CDS	−0.53‡	−0.58‡	−0.10	−0.03	0.07	−0.27	−0.27	−0.38	−0.27	−0.07	0.00
CPT	−0.48§	−0.53‡	0.04	−0.02	−0.18	0.06	0.04	−0.08	−0.12	0.17	0.31
LRS	−0.40	−0.30	−0.23	−0.13	−0.48§	−0.07	−0.04	−0.39	−0.34	−0.18	−0.11
MTG	−0.45§	−0.55‡	−0.19	−0.14	−0.05	−0.38	−0.38	−0.23	−0.33	−0.15	0.16
PRO	−0.23	−0.33	−0.47§	−0.48§	−0.11	−0.40	−0.35	−0.17	−0.29	0.10	0.05
AC											
CPT	0.45§	0.52‡	0.14	0.02	0.33	0.08	0.19	0.23	0.52‡	−0.09	−0.08
MTG	−0.34	−0.26	−0.31	−0.15	−0.39	0.21	0.22	0.02	−0.22	0.04	0.02
MTH	0.44§	0.46§	0.12	0.02	0.08	0.35	0.38	0.68‡	0.60‡	0.27	0.23
SPD	0.54‡	0.49§	0.00	0.04	0.18	0.29	0.45§	0.40	0.56‡	0.08	−0.02
TP											
CDD	0.55‡	0.60‡	0.29	0.26	0.13	0.33	0.31	0.38	0.54‡	−0.10	−0.06
CDS	0.45§	0.54‡	0.42§	0.39	−0.01	0.50§	0.42§	0.52‡	0.51‡	0.39	0.41§
CPT	0.51‡	0.66‡	0.35	0.20	0.18	0.26	0.21	0.53‡	0.74‡	0.24	0.20
LRS	0.58‡	0.52‡	0.46§	0.36	0.48§	0.20	0.06	0.57‡	0.45§	0.38	0.44§
MTH	0.54‡	0.62‡	0.30	0.22	0.22	0.45§	0.31	0.45§	0.55‡	0.34	0.18
PRO	0.28	0.41§	0.26	0.22	0.20	0.24	0.17	0.30	0.45§	−0.22	−0.13
SPD	0.36	0.32	0.16	0.13	0.04	0.43§	0.28	0.42§	0.21	0.30	0.19
STN	0.34	0.54‡	0.21	0.24	−0.08	0.22	0.04	0.27	0.38	0.21	0.00

* Values are the partial Pearson's correlation coefficient after adjustment for age. Ped-ANAM performance parameters without significant correlations to the respective formal neuropsychological test are not presented in the table. CMS-I = Stories Subtest of the Children's Memory Scale, Immediate Recall Trials; CMS-D = Stories Subtest of the Children's Memory Scale, Delayed Recall Trials; ROCF-I = Rey Osterrieth Complex Figure, immediate recall trial; ROCF-D = Rey Osterrieth Complex Figure, delayed recall trial; ROCF-C = Rey Osterrieth Complex Figure, copy trial; Trail-A = Trail Making Test Part A; Trail-B = Trail Making Test Part B; CW-I = Delis Kaplan Executive Functioning System, Color-Word—interference subtest; CW-IS = Delis Kaplan Executive Functioning System, Color-Word–interference/substitution subtest; CW-CN = Delis Kaplan Executive Functioning System, Color-Word—color naming subtest; CW-R = Delis Kaplan Executive Functioning System, Color-Word—color reading subtest; MNc = mean reaction time required to present a correct answer; CVc = coefficient of variation of time to correct response; AC = accuracy; TP = throughput; see Table 1 for additional definitions.
† Z score values are correlated with Ped-ANAM performance parameters.
‡ Significant correlation coefficient with $P < 0.01$.
§ Significant correlation coefficient with $P < 0.05$.

identify NCD and possibly the responsiveness to change could be improved if some of the Ped-ANAM test items had higher difficulty levels, resulting in decreased skewness of distribution of AC values. Given the versatility of the Ped-ANAM, this hypothesis could be easily tested after changing the respective test settings of the metrics.

In this convenience sample of patients diagnosed with childhood-onset SLE, only 3 of the 10 Ped-ANAM tests (SPD, CPT, MTH) appeared to be especially informative for the presence of NCD. Given the size of the study population and the recruitment strategy used, it appears premature to eliminate the other Ped-ANAM tests from future studies in children with SLE. Because sensitivity and specificity of a measure depend on the prevalence of a condition in the studied population, estimates of sensitivity, specificity, and the AUC determined in this study will likely differ when the Ped-ANAM is used in other pediatric SLE cohorts. Nonetheless, we think that the Ped-ANAM is a useful screening tool for NCD because the frequency of NCD among the study participants was comparable with that in previous studies (2,28), and all study participants were clinically asymptomatic for NCD, making a diagnosis of NCD conceivably more difficult than that of overt impairment. However, severe NCD can more easily be identified in a clinical setting and the objectives of the study were to assess the potential of the Ped-ANAM to screen for mild, clinically hard to diagnose NCD.

It is interesting that the ROCF measures discriminated between the cognitively impaired and unimpaired groups, but had few significant correlations with the ANAM pa-

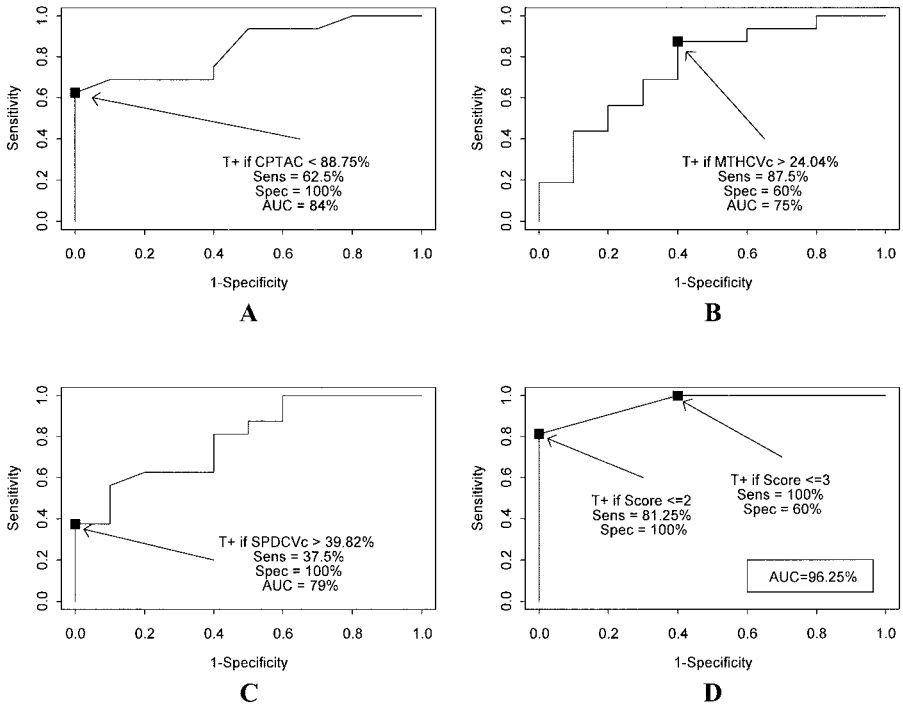

Figure 1. Receiver operating characteristic curve (ROC) analysis. ROC curves were constructed and are depicted for **A,** accuracy of continuous performance test (CPT-AC), **B,** coefficient of variation of reaction to correct response time of math processing test (MTH-CVc), and **C,** coefficient of variation of reaction to correct response time of spatial processing test (SPD-CVc) to assess the usefulness of these parameters when used by themselves. **D,** Test results of the 3 Automated Neuropsychological Assessment Metrics pediatric battery (Ped-ANAM) parameters are used in combination based on the results of the classification and regression tree model. The area under the ROC curve (AUC) for the combined assessment of CPT-AC, MTH-CVc, and SPD-CVc results in an AUC of 96.25%. Score = 1: CPT-AC $\leq$ 88.75%; score = 2: CPT-AC $>$ 88.75% but MTH-CVc $>$ 24.04% and SPD-CVc $>$ 39.82%; score = 3: CPT-AC $>$ 88.75% and MTH-CVc $>$ 24.04% but SPD-CVc $\leq$ 39.82%; score = 4: both CPT-AC $>$ 88.75% and MTH-CVc $\leq$ 24.04%. Sens = sensitivity; Spec = specificity.

rameters. Although speculative, this result may suggest somewhat different ways in which these tests are sensitive to NCD. The ROCF is considered a complex, multicomponential test that reflects several latent neuropsychological processes (visuoconstruction, visuoperception, graphomotor coordination, executive functions, memory) while underemphasizing rapid and efficient processing speed. Conversely, the ANAM tends to be simpler (fewer neuropsychology components) with a premium placed on speed and efficiency. If correct, then the prediction of NCD would be maximized by combining both types of tests. Addressing this issue, however, is beyond the scope of the current study and will need to be addressed in more detail in future investigations.

A limitation of our study may be that many participants were older than 16 years at the time of the study. In particular, we do not know the youngest age at which the Ped-ANAM can be administered. The youngest participant of the present study was 10 years old and did not have any difficulty performing the Ped-ANAM tasks. Due to the small number of younger participants, a subanalysis stratified by age was not possible. Nonetheless, we suspect that suitable cutoff values of Ped-ANAM parameters best suited for diagnosing NCD are dependent on patient age. However, this effect could not be tested in this initial validation study.

In summary, the Ped-ANAM, when used in childhood-onset SLE, has concurrent validity and promising sensitivity and specificity to diagnosing NCD. The results of this study require confirmation in a larger group of children with SLE to verify the measurement properties of the Ped-ANAM. Although the ANAM is thought to be devoid of a training effect, additional research is necessary to confirm the consistency (test–retest reliability) of the Ped-ANAM. Additionally, the ability of the Ped-ANAM to capture clinically relevant change in cognition requires further investigation.

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AUTHOR CONTRIBUTIONS

Dr. Brunner had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study design. Brunner, Ruth, Passo, Roebuck-Spencer, Ris.
Acquisition of data. Brunner, Ruth, German, Nelson, Passo, Ris.
Analysis and interpretation of data. Brunner, Nelson, Roebuck-Spencer, Ying, Ris.
Manuscript preparation. Brunner, Nelson, Roebuck-Spencer, Ying, Ris.
Statistical analysis. Brunner, Ying.

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Project D4: "Does Constraint-Induced Movement Therapy Improve Upper Extremity Motor Function in Individuals Following Stroke?"

Upper extremity amputees adapt to their prostheses during reaching movements, but exhibit abnormalities with their intact arm

Keywords: Amputee, Prosthetics, Reaching, Vision, Proprioception, Motor Control

Metzger AM, Lum PS, Schabowky CN, Holley RJ, Monroe B and Dromerick AW

Abstract

This study investigated the role of vision in upper extremity reaching movements of unilateral below elbow prosthetic users. Subjects used a robotic manipulandum to reach to two targets, one contralateral and one ipsilateral, located in a horizontal plane. These trials were performed with both the prosthetic arm and the intact arm. Visual guidance was then eliminated from the environment and the subjects had to reach to the same targets, relying on their sense of proprioception. Endpoint error, trajectory error and variability were calculated and compared to that of control subjects. We predicted that performance of the prosthetic device would be less accurate than controls and that the intact arm would be comparable to normal performance. Contrary to our hypothesis, results showed no significant difference between the performance of the prosthetic arm and the controls in the vision and no-vision conditions. Analysis did however reveal significant abnormalities in performance of the intact limb. When compared to controls, the intact arm of the prosthetic users had significantly larger medial endpoint errors for the ipsilateral target without visual guidance ($P = 0.001$). This was consistent with data from the intact arm in the vision condition, where a significantly larger medial trajectory error ($P = 0.003$) was found. In the vision condition, this trajectory error was corrected with visual feedback, which allowed the subjects to correct their errors and complete the reach without endpoint error. The intact arms also demonstrated significantly higher variability in their reaching endpoints in the no-vision condition. ($P = 0.010$). These findings regarding the prosthetic arm reveal an adaptation to the altered inertial properties of the arm. The findings regarding the intact arm may reflect the cortical reorganization that occurs after amputation of a limb, which is consistent with recent theories regarding hemispheric lateralization of motor control.

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RESEARCH ARTICLE

Trans-radial upper extremity amputees are capable of adapting to a novel dynamic environment

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Abstract This study investigated differences in adaptation to a novel dynamic environment between eight trans-radial upper extremity (UE) prosthetic users and eight naive, neurologically intact subjects. Participants held onto the handle of a robotic manipulandum and executed reaching movements within a horizontal plane following a pseudo-random sequence of targets. Curl field perturbations were imposed by the robot motors, and we compared the rate and quality of adaptation between the prosthetic and control subjects. Adaptation was quantitatively assessed by peak error, defined as the maximum orthogonal distance between an observed trajectory and an ideal straight trajectory. Initial exposure to the curl field resulted in large errors, and as the subjects adapted to the novel environment, the errors decreased. During the early phase of adaptation, group differences in the rate of motor adaptation were not significant. However, during late learning, both error magnitude and variability were larger in the prosthetic group. The quality of adaptation, as indicated by the magnitude of the aftereffects, was similar between groups. We conclude that in persons with trans-radial arm amputation, motor adaptation to curl fields during reaching is similar to unimpaired individuals. These findings are discussed in relation to mechanisms of motor adaptation, neural plasticity following an upper extremity amputation (UEA), and potential motor recovery therapies for prosthetic users.

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Introduction

Most amputees do not become proficient users of their prosthesis and only a small percentage become skilled and consistent prosthetic users (Dudkiewicz et al. 2004; Nielsen et al. 1989). The National Center for Health Statistics reports 30–50% of amputees do not wear their prosthetic hand on a regular basis. The identified concerns include lack of education about options and care, lack of training, discomfort, poor cosmetics, and cost (Nielsen 1991; Melendez and LeBlanc 1988). Investigating deficits in motor control following an upper extremity amputation may identify some of the many reasons why upper extremity amputees do not embrace current prosthetic devices. This work may lead to better training methods, and improved training may have an important role in ameliorating the high rate of treatment failure.

Trans-radial upper extremity amputation (UEA) causes deficits in both the musculoskeletal and neural systems making previously effortless tasks more difficult. In

unimpaired persons, these tasks involve intact function and communication between the neural and musculoskeletal systems that result in smooth coordination of multiple joints. Such performance implies that the nervous system accounts for the biomechanical properties of the arm, including geometry, mass and inertia, to send proper activation signals to muscles in both a predictive (feedforward) and corrective (feedback) manner. Once these signals have been received, muscles produce the required forces to complete the current task.

Following UEA, not only is a physical segment of the body lost, but also sensory information concerning state of the musculoskeletal system is impaired due to lost muscle spindles, Golgi tendon organs, and cutaneous skin receptors. Loss of distal proprioception presumably requires prosthetic users to heavily rely on the slower, less automated visual feedback process, increasing the computational load for prosthetic integrated motor control (Soede 1982). There is also evidence of neural reorganization in both the somatosensory (Flor et al. 1995; Grüsser et al. 2001) and motor (Hall et al. 1990; Cohen et al. 1991) cortices following amputation. Specifically, studies have shown that adjacent representations tend to "invade" the recently deafferented hand representation area (Roricht et al. 1999; Irlbacher et al. 2002). Such neural plasticity can be frequently accompanied by a painful or nonpainful sensation that the missing hand is still present, commonly known as phantom limb phenomena (Wall and Gutnick 1974). Although the effects of amputation on the musculoskeletal and neural systems are well documented, it is unknown how these changes may affect motor control and learning.

To investigate and develop beneficial training techniques for UEA prosthetic users, it is important to consider recent findings in motor learning. Humans have the ability to quickly adapt to changes in external forces caused by a large variety of dynamic environments and tools encountered on a daily basis. Contemporary motor adaptation studies have focused on the use of robotics to examine the ability to adapt to novel dynamic environments. In this setting, subjects perform reaching tasks in force fields applied to the hand via a robotic manipulandum. These forces alter the dynamics of a reaching task, greatly distorting previously straight hand trajectories. With practice, the central nervous system learns to compensate for the perturbing forces by altering the feedforward commands initiating the reaching movements. These feedforward commands are the result of an internal model of the force field that develops during repeated exposure to the novel environment (Shadmehr and Mussa-Ivaldi 1994; Lackner and Dizio 1994). This is achieved by recalling the perturbation strengths and resulting hand-path errors of the preceding reaching movement(s) to update the internal model and eventually straighten subsequent reaching movements (Thoroughman and Shadmehr 2000; Scheidt et al. 2001).

Though impedance control strategies (stiffening the arm) could explain this phenomenon (Schabowsky et al. 2007; Franklin et al. 2003; Milner and Franklin 2005), the existence of aftereffects supports the idea of internal models. An aftereffect occurs when the perturbing field is unexpectedly removed during a "catch trial." The hand path of an aftereffect tends to resemble a mirror image of the distorted hand path caused by initial force field exposure. This implies that subjects are actively predicting and compensating for the novel environment rather than simply stiffening their arm (Flanagan and Wing 1997). As the internal model develops, aftereffects become larger (Conditt et al. 1997). Thus, repetition (i.e. practice) leads to improved adaptation to a novel dynamic environment.

Numerous motor tasks are learned in a similar fashion and these internal models can then be recalled under the appropriate conditions (Brashers-Krug et al. 1996; Shadmehr and Brashers-Krug 1997; Caithness et al. 2004). Investigating motor adaptation can also have direct implications to therapeutic practice. For instance, similar experiments have investigated stroke victims' impaired ability to predict and adapt to changes in external loads (Patton et al. 2006; Scheidt and Stoeckmann 2007) and it is thought that this impairment may be a key hindrance to motor recovery (Takahashi and Reinkensmeyer 2003).

Our group is interested in investigating UE prosthetic users' ability to formulate internal models while adapting to a novel dynamic environment. Proper adaptation requires internal models of both the novel environment and the limb segments used in the task. We chose to first study the simplest case: internal model formation during tasks involving intact joints in persons with below-elbow amputations. We ask: does distal amputation of the upper extremity and subsequent neural reorganization compromise internal model formation? Consequently, could therapy sessions specifically designed to promote accurate internal model formation through repetition be effective for this population?

Materials and methods

Subjects

Sixteen subjects, eight controls and eight trans-radial upper extremity (UE) prosthetic users, were examined. All subjects signed an informed consent form prior to admission to the study. Every protocol was approved by the National

Rehabilitation Hospital's Internal Review Board for Protection of Human Subjects. Under this paradigm, the experimental group's prosthetic arms were tested. Six dominant and two non-dominant limbs were tested in each group (for the prosthetic group, dominance refers to the pre-injury state). The average age of the two subject groups were not significantly different ($P > 0.05$).

Table 1 summarizes the prosthetic users' clinical data. The mean subject age was 50.2 ± 14 years and all UEA participants were at least two years post amputation. Six subjects had amputations on the right forearm, while two subjects had amputations on the left forearm. Seven prosthetic users wore body powered devices and one subject wore a myoelectric prosthetic device. The injury of Subject 2 occurred at 6 months of age, before dominance was established. All other subjects were right handed prior to injury. An occupational therapist examined clinical proprioception by requiring subjects to identify the direction of imposed movements of the elbow without vision. Also, cutaneous sensation was assessed with Semmes-Weinstein monofilaments. All subjects had clinical proprioception and cutaneous sensation at the site of injury.

Prosthetic arms

This experiment tested only below-elbow amputees. A trans-radial prosthetic device is attached to the stump of the user's residual limb. The prosthetic device replaces the missing distal forearm, wrist and hand. Wrist movement is controlled by manually positioning and locking the end effector at different angles. The end effector of the body-powered devices is actively opened by a cable system that is driven by contralateral shoulder girdle movement. Protracting the shoulder contralateral to the prosthetic arm draws on the cable to open the hook. Shoulder retraction closes the hook. To ensure that prosthetic users constantly gripped the manipulandum's handle, the cable system was detached so the hook gripped onto the handle firmly throughout the test session (elastic bands around the hook provided the grip force). For the myoelectric user, the myoelectric controls were deactivated to ensure that the hook gripped the handle at all times. None of the degrees of freedom used for normal arm reaching movements were compromised to control the prosthetic devices.

To confirm that the inertial properties of the prosthetic arm were different from a normal limb, we measured the mass, center of mass and moment of inertia (pendulum method) of a typical body-powered prosthesis and compared these values with tabulated values for the forearm and hand of a 180 lb male with forearm length that matched the forearm length of the prosthesis (Winter 1990). The center of mass of the prosthesis was nearly identical to that of the human forearm and hand. However, the mass and moment of inertia of the prosthesis were only 49% and 39% of a normal human limb, respectively. If the residual stump is added to the prosthesis, the mass and moment of inertia of the prosthesis-stump would increase closer to normal; however, the center of mass of the prosthesis-stump moves closer to the elbow compared to that of the normal limb.

Experimental setup

This study used the planar, two degree of freedom robot, InMotion^2 (Interactive Motion Technologies, Inc, Cambridge, MA, USA). Reaching movements occurred within a 70 cm × 40 cm workspace. As an added safety measure, LED sensors (World Beam Q12 series, Banner Engineering Corp.) were positioned about the perimeter of the workspace. If the handle of the robot moved outside of

Table 1 Prosthetic group clinical summary

Subject	Age (years)	Chronicity (years)	Nine Hole Peg Test (s)	Prosthetic type	Phantom sensation	Stump proprioception	Amputated arm[a]
1	36	2.8	109.22	Body powered—hook	Yes; sensation and pain	Intact	Left, ND
2	51	50	103.41	Body powered—hand	No	Intact	Right, N/A
3	42	5.6	80	Body powered—hook	Yes; sensation and pain	Intact	Right, D
4	46	2	118.485	Body powered—hook	No	Intact	Left, ND
5	67	45	45.265	Body powered—hook	No	Intact	Right, D
6	68	53	42.17	Body powered—hook	No	Intact	Bilateral
7	61	40	63	Body powered—hook	Yes; sensation and no pain	Intact	Bilateral
8	31	12.4	114.5	Myoelectric—hook	Yes; sensation and pain	Intact	Right, D

[a] Dominance is denoted by a D (dominant arm) and ND (nondominant arm). Amputation of Subject 2 occurred at 6 months of age before dominance was established

the designated workspace, the sensors would trigger an emergency stop and turn off the motors. Custom programs (Matlab 7.1, XPCtarget 2.8; The MathWorks Inc, Natick, MA, USA) were used to control the robot. Also, an inverse dynamics algorithm was used to partially compensate for the inertia of the robot links, dramatically decreasing the intrinsic anisotropy of the robot. The forces applied to the hand by the robot were measured with a force sensor during the movements used in this study. With inertial compensation, the peak resistance force imposed by the robot was reduced from 13.5 to 7.5 N. Most importantly, the maximum difference between peak forces in the 3 tested movement directions was reduced from 9 to 3 N and lateral forces never exceeded ±1 N.

Subjects seated in an adjustable chair held onto the handle of the robot and executed reaching movements within a horizontal plane. For comfort, the handle was positioned slightly below shoulder height. All participants were fitted with a shoulder harness that consisted of two shoulder straps attached together by a waist strap. All three straps were tightened to a snug but comfortable position. This harness minimized any torso movement and ensured that reaching movements were performing predominantly by glenohumeral and elbow joint rotations. A splint supported the subject's forearm and/or prosthesis and straps restricted wrist rotation. Figure 1a and b illustrates how the prosthetic group and control group subjects gripped the robot handle. The end effector (hook) grasped the cylindrical handle firmly and two Velcro straps attached the forearm to the splint. The forearm, hand/gripper and splint can be considered a rigid body in all subjects. The splint is attached to the robot, which provides support against gravity and allows movement in the horizontal plane. Each subject was positioned with the shoulder in 60° of horizontal adduction (Θ_S) and the elbow flexed 60° (Θ_E) as the subject held the handle in the start position. Subjects performed reaching movements while viewing an eye level computer screen and could see their arm throughout this experiment.

Under some conditions, the robot created a velocity dependent force field, or curl field. To produce this field, the robot applied forces (*Fx, Fy*) to the handle that were orthogonal to its velocity (v_x, v_y) (Eq. 1). All tested arms experienced a counterclockwise (CCW) field (Fig. 1d).

$$\text{CCW curl field} \Rightarrow \begin{bmatrix} Fx \\ Fy \end{bmatrix} = \begin{bmatrix} 0 & 20 \\ -20 & 0 \end{bmatrix} \begin{bmatrix} v_x \\ v_y \end{bmatrix} \quad (1)$$

Experimental tasks

Subjects performed consecutive "center out and back" reaching movements following a pseudorandom sequence of targets. Throughout this experiment, handle position and the desired targets were displayed (real time) as colored

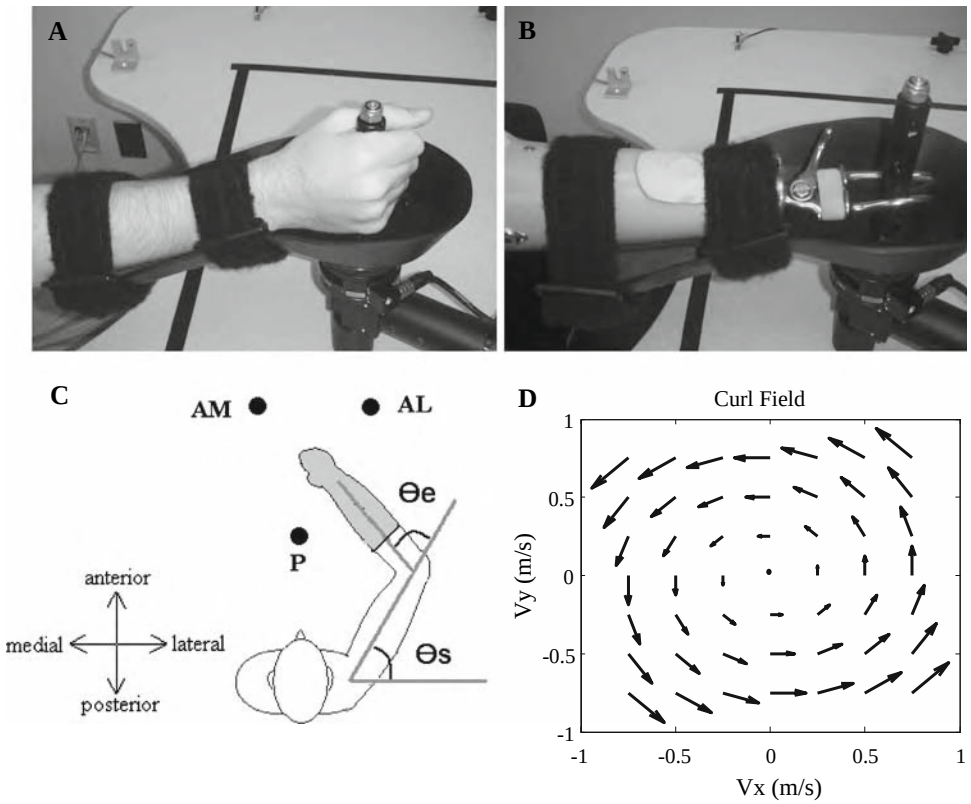

Fig. 1 **a** Picture of the arm support for intact arm. **b** The same arm support being used by an amputee. **c** Top view of the experimental setup: Testing began with subjects holding a robotic manipulandum (not shown) at a central start point oriented along the subject's midline. Subjects were positioned so that Θ_S and Θ_E were 60°. Target AM, target AL and target P were positioned at 45°, 135° and 270° relative to the medial-lateral axis. **d** Forces exerted by robot while subjects performed reaching movements within the novel dynamic environment (counterclockwise field)

circles with diameters of 1 cm. Three targets were positioned 10 cm radial to a start position that was oriented along the subject's midline. When testing the right arm, target AL (anterior–lateral), target AM (anterior–medial), and target P (posterior) were positioned at 45°, 135° and 270° relative to the medial–lateral axis (Fig. 1c). The 10 cm movements were approximately 42% of the maximum reach in these directions. To induce perturbation effect symmetry, target AL and target AM were switched when the left arm was tested. Each subject was instructed to perform rapid reaching movements to the target. Only the "center out" reaching movements were analyzed and the return movements were not considered. Feedback was provided to encourage subjects to perform reaching tasks with consistent peak tangential velocities. After a trial, the target circle changed color: white signaled that the reaching movement fell within the desired peak tangential velocity range (45–55 cm/s); green and red signaled that movements were too slow or fast, respectively. All movements were included in the analysis even if they were outside of the target velocity range. The monitor was vertical and "up" represented forward in the workspace. Also, distances were scaled down by a factor of 2/3 on the monitor.

Every subject performed reaching movements under three conditions. Subjects executed a total of 30 reaching movements within the null field to become familiarized with the experimental setup and practice reaching within the desired peak tangential velocity range. Under this condition, the motors were active but only provided compensation for the inertia of the robot links. After familiarization, subjects completed a total of 120 trials within the curl field. During this training condition, the curl field was active for both center out and return movements. Finally, subjects performed a total of 90 reaching movements in the third condition. This final condition produced the same curl field, but introduced catch trials. Occurring pseudo-randomly (mean = 1 of 6 trials), the catch trials removed the curl field and induced aftereffects by unexpectedly reintroducing subjects to the null environment.

Prosthetic subjects were evaluated by the Nine Hole Peg Test, a standardized clinical assessment of arm motor control (Mathiowetz et al. 1985). This test requires subjects to place nine pegs (9 mm diameter and 32 mm long) into nine holes and then remove the pegs from the holes. The outcome measure of this evaluation is the amount of time required to place and remove all nine pegs (Table 1).

Data analysis

For each reaching task, custom software recorded the position of the handle measured by the robot's encoders. These signals were digitally differentiated and low pass Butterworth-filtered ($f_S = 1$ kHz, $f_C = 30$ Hz, second order) to yield hand tangential velocity. The initiation and cessation of movement was defined as 5% of the maximum tangential velocity. Adaptation was quantitatively assessed by peak error, defined as the maximum orthogonal distance between an observed trajectory and an ideal straight trajectory. Typically, the peak error occurred at maximum tangential velocity and within the first 200 ms of the movement.

In all three experimental conditions, analysis focused on the peak velocity and the time and magnitude of the peak error. For every subject in all conditions, target specific mean values of each metric were calculated. To analyze null field performance, repeated-measures two-way ANOVA was performed with target direction as the within factor and limb type (prosthetic, intact) as a between subjects factor. Motor adaptation analysis was separated into early and late learning. Since the majority of the adaptation occurred during the first 30–40 trials in the curl field, early learning analysis focused on these trials. For each target, the peak errors during early learning were analyzed with repeated-measures two-way ANOVA. The within-subject factor was trial number and the between-subject factor was limb type. Each subject's performance during late learning was quantified by the mean and standard deviation of the peak errors from all late learning trials; then group differences were analyzed with two-tailed, unpaired t-tests. The rationale and justification for compartmentalizing the motor adaptation time course into early and late learning phases is provided in the results section. Aftereffects were compared with repeated-measures two-way ANOVA with target direction as the within factor and limb type (prosthetic, intact) as a between subjects factor. For all repeated-measures ANOVAs, Mauchly's test of sphericity was used to validate the assumption of sphericity. If the assumption of sphericity was not valid, the Greenhouse–Geisser correction factor was used. Significant effects were further examined with Bonferroni-corrected *T*-tests.

Results

Analysis of reaching movement performance during the null field experiment showed no significant differences between the prosthetic group and control group (Fig. 2a). Without the robot's interference, both groups were capable of performing smooth, straight reaching movements in close proximity to the desired peak velocity range (45–55 cm/s). Overall, the mean peak velocities for the prosthetic and control groups were 43.3 ± 1.4 and 45.7 ± 1.0 cm/s (mean $\pm$ SE) (Fig. 2b). Repeated-measures two-way ANOVA indicated the limb type effect ($P = 0.11$) and the target direction $\times$ limb type interaction ($P = 0.57$) were not significant. The mean peak errors for

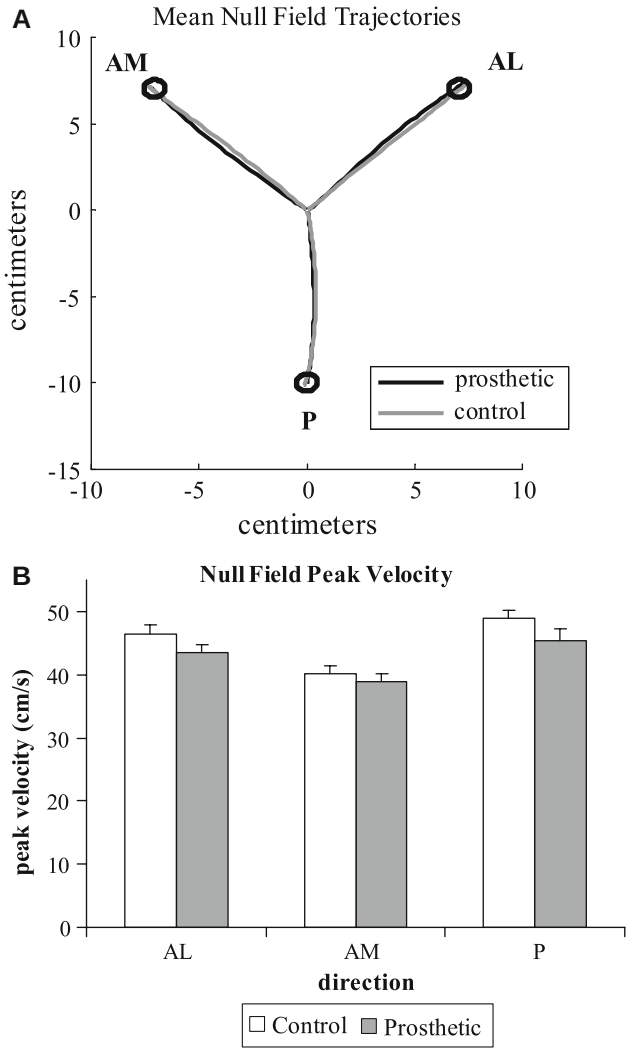

Fig. 2 **a** Mean reaching movement trajectories for both the prosthetic and control groups. The prosthetic group was capable of performing stereotypical straight, smooth reaching movements toward all targets. **b** Mean peak velocities separated by direction

the prosthetic and control groups in all directions were 0.70 ± 0.03 and 0.67 ± 0.04 cm, respectively. Repeated-measures two-way ANOVA found that limb type ($P = 0.71$) and the target direction × limb type interaction were not significant ($P = 0.64$). The mean time of peak error for the prosthetic and control groups were 182 ± 4 and 165 ± 6 ms, and fell within the time before voluntary reaction could cause significant error correction. Thus, both groups performed reaching movements in the null field with comparable speed and accuracy.

For the curl field experiment, the prosthetic and control groups performed reaching movements with similar velocities. Mean peak velocities for the prosthetic (48.4 ± 1.8 cm/s) and control (50.7 ± 0.84 cm/s) groups were within the desired range of 45–55 cm/s. Repeated-measures two-way ANOVA indicated that effect of limb type ($P = 0.28$) and the target direction × limb type interaction were not significant ($P = 0.89$). To assess the within-subject variability in peak velocity, 99% confidence intervals on velocity were calculated for each subject during the adaptation phase. The size of these intervals were smaller than the target range of 10 cm/s, ranging from 5.7 to 3.4 cm/s. The mean time of peak error for the prosthetic group (188 ± 5 ms) and control group (176 ± 4 ms) were not significantly different. This data shows that all subjects' reaching movements within the curl field were exposed to equivalent perturbation forces.

Figure 3b displays the group averages of the entire time course of adaptation. Visual inspection shows that the majority of error is corrected during the first 30–40 reaching movements within the force field. This period is commonly deemed the early learning phase. Following early learning of the dynamic environment, late learning consisted of a plateau of fairly steady peak errors. The perturbation effects of the dynamic force field are dependent on movement direction and workspace location. This explains the seemingly large variance during motor adaptation as subjects reached to different targets. To account for the directionally dependent perturbation effects, further analysis of the rate of adaptation was target specific.

Figure 4 illustrates the target specific, mean reaching trajectories of both the prosthetic group and control group. For averaging and visualization purposes, the trajectories performed by the left arm toward target AL and target AM were rotated and aligned with the corresponding targets for the right arm. Inspection of this figure highlights the similar response to the dynamic force field between groups. Typically, the first exposure to the force field induced the largest peak error. After performing a number of reaching movements within the force field, peak error was greatly reduced and the final exposure trajectories resembled null field trajectories (recall Fig. 2a). Also, mean aftereffect responses during catch trials closely resembled a mirror image of the initial exposure trajectories.

Figure 5 presents the entire time course of motor adaptation for each target direction. For all targets, the majority of error reduction occurred during the first ten reaching movements (the first 35 consecutive reaching movements). During this interval, approximately 89% of the total error correction had been achieved. Accordingly, the first ten reaching movements toward each target were designated as the early learning phase and all subsequent trials deemed the late learning phase.

The early learning phase of motor adaptation was analyzed using repeated-measures two-way ANOVA. For all target directions, the limb effect was not significant ($P > 0.41$; post hoc power was 0.09, 0.09 and 0.13 for the

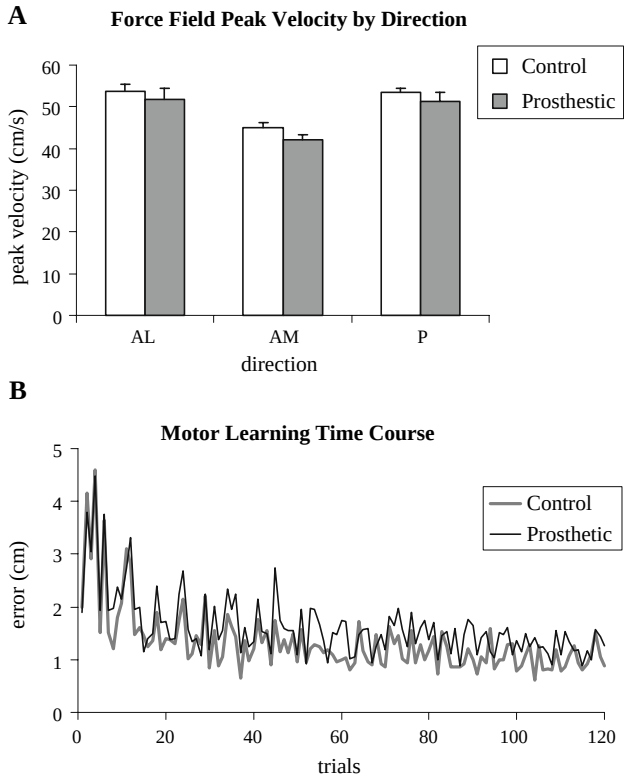

Fig. 3 **a** Mean peak velocities separated by direction. Peak velocities were directionally dependent for both groups. **b** Mean learning patterns for both the prosthetic group and control group. Further analysis of motor learning was target specific

three directions), indicating that peak error magnitudes were similar between groups. The effect of trial number was significant for all targets ($P < 0.001$), signifying that motor adaptation was taking place and errors were decreasing with each additional exposure to the dynamic environment. Also, the trial × limb type interaction was not significant for any direction ($P > 0.15$; post hoc power was 0.7, 0.19 and 0.24 for directions AL, AM and P, respectively), demonstrating that the pattern of error decrement was similar for both the prosthetic and control groups.

Late learning adaptation levels were examined by calculating each subject's mean error over the entire late learning period (trials 36–120). Late learning errors were significantly larger ($P = 0.008$) in the prosthetic group (1.43 ± 0.07 cm) compared to the control group (1.11 ± 0.07). Late learning errors in the prosthetic group were $28 \pm 3\%$ larger than controls. Late learning performance variability was assessed by examining the within-subject standard deviations in the peak error data. Error variability was significantly higher ($P = 0.01$) in the prosthetic group (0.70 ± 0.04 cm) than in the control group (0.55 ± 0.03 cm). Late learning variability in the prosthetic group was $27 \pm 3\%$ larger than controls.

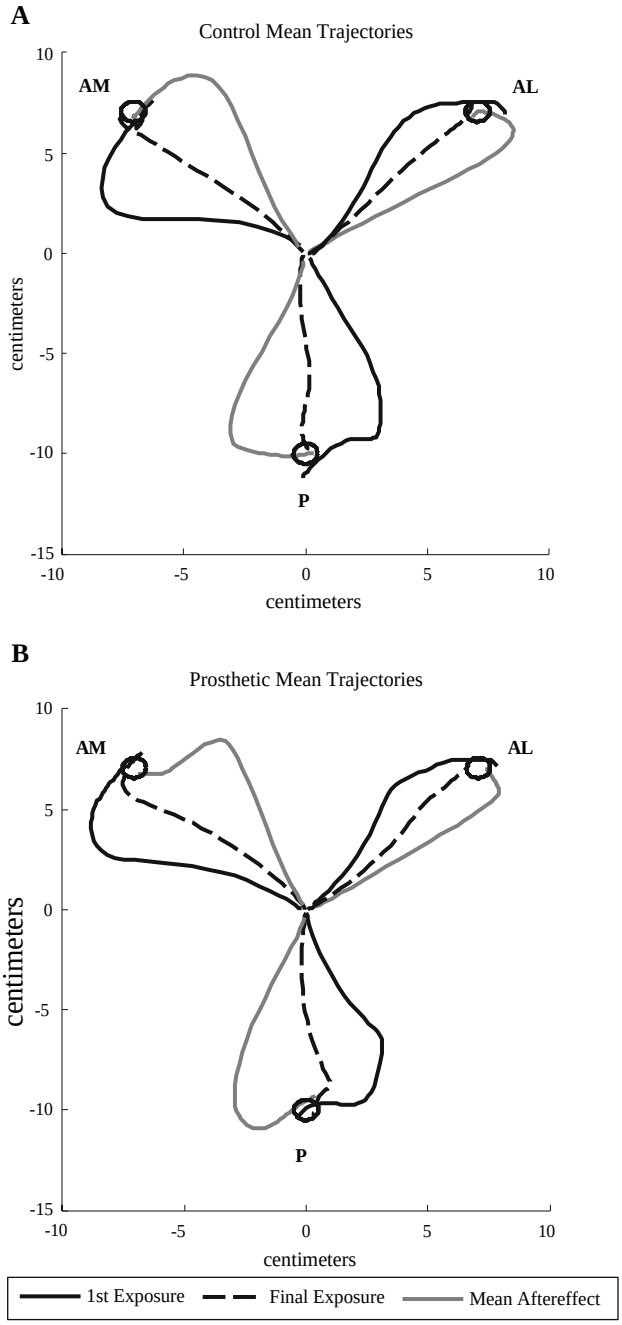

Fig. 4 The mean trajectories across subjects of the first exposure, last exposure and aftereffect for the reaching movements in the AL, AM, and P targets in the (**a**) control group and (**b**) prosthetic group. Nondominant arm reaching trajectories were rotated for averaging and visualization purposes

A complementary analysis was performed on the aftereffect errors induced by the catch trials during the final experiment. Figure 6a illustrates the mean peak velocities for each target. Movements performed during the catch trials resulted in mean peak velocities of 54.8 ± 1.4 and 57.2 ± 2.2 cm/s for the prosthetic and control groups. Repeated-measures two-way ANOVA of the peak velocities

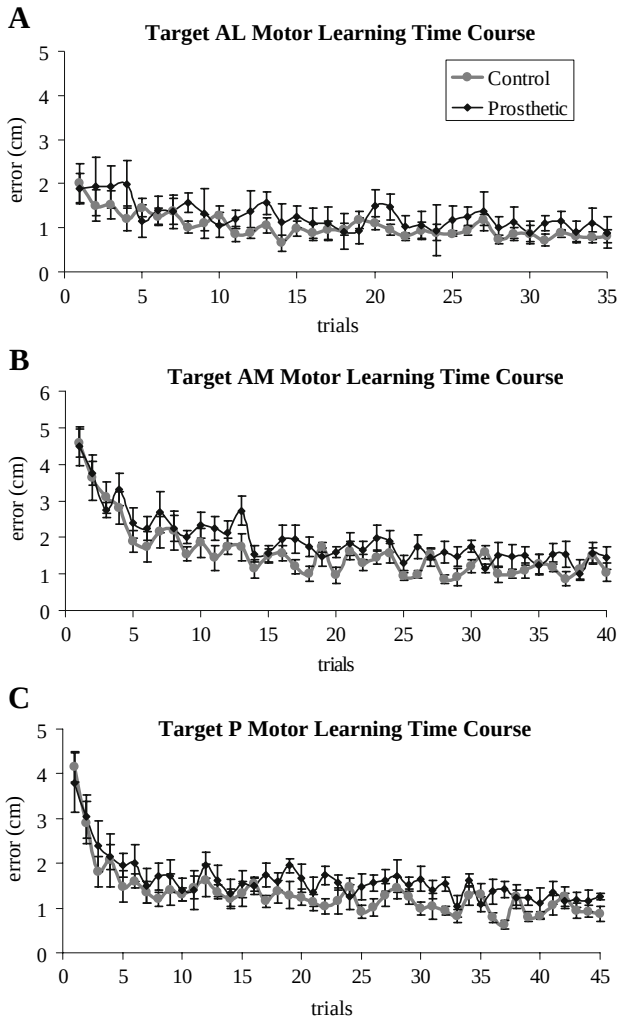

Fig. 5 Target specific motor learning time course for (**a**) target AL (**b**) target AM and (**c**) target P. For all target directions, the majority of peak error is reduced by the tenth trial. *Errors bars* denote standard error

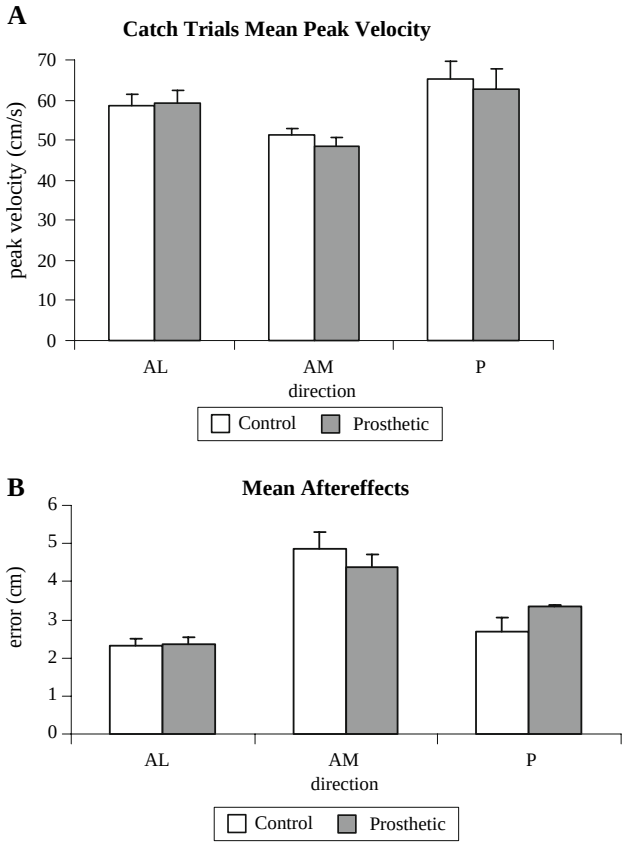

Fig. 6 **a** Peak velocities and **b** aftereffects for each of the directions. No group differences were found for either variable

indicated no differences between the prosthetic and control groups; the limb type effect ($P = 0.64$) and the target direction × limb type interaction ($P = 0.82$) were not significant. Repeated-measures two-way ANOVA of the aftereffect errors indicated that the limb effect ($P = 0.8$, post hoc power = 0.06) and the direction × limb interaction were not significant ($P = 0.12$, post hoc power = 0.43) (Fig. 6b). The direction effect was significant ($P < 0.001$), and Bonferroni-corrected *t*-tests indicated that aftereffects were largest in the AM direction ($P < 0.001$) and smallest in the AL direction ($P < 0.03$).

To minimize the possible effects of between-group differences in limb inertia, we calculated the ratio of the catch trial errors (mean of first three catch trials) to initial curl field errors (mean of first three curl field exposures). When averaged over all directions, the magnitude of these ratios were 1.16 ± 0.08 for the prosthetic group and 1.06 ± 0.07 for the control group. A repeated-measures two-way ANOVA of these ratios found that the limb effect was not significant ($P = 0.40$), and the direction × limb interaction was not significant ($P = 0.41$). This indicates that the groups' aftereffect magnitudes were equivalent.

We examined 95% confidence intervals on the metrics that showed no significant group differences, rate of early learning and size of aftereffects. Results indicated that with 95% confidence, the prosthetic group aftereffects were within 0.41 cm of controls, which represents a group difference of less than 12.4% (normalized by the average control group after effects). To quantify learning rates in each subject, exponential fits were performed on peak errors as a function of trial number. The learning rates were highly variable across subjects (range of 0.02–0.17), and while learning rates were not significantly different between groups, the high variability resulted in large confidence intervals. Based on the current data set, there was 95% confidence that the learning rate of the prosthetic group was within 0.057 of controls, which represents a group difference of less than 63% (normalized by the average control group learning rate).

Correlation analysis was performed between subject characteristics (Nine Hole Peg Test, chronicity) and

performance variables (late learning error, late learning variability, aftereffect size) in the prosthetic group. Scores on the Nine Hole Peg Test ranged from 118 s for poor users to times approaching 40 s for highly functional users. For comparison, normative values for 46 to 55-year-old males range from 18–20 sec (Oxford Grice et al. 2003). There was a significant correlation between time on the Nine Hole Peg Test and size of aftereffects ($r = 0.86$, $P = 0.04$, Bonferoni-corrected for multiple correlations), indicating that subjects with poorer functional ability had larger aftereffects. None of the other correlations were significant.

Discussion

This study investigated differences in motor adaptation between trans-radial UE prosthetic users and a control group. In most of the measures we examined, we found that the performance of these two groups was comparable. Without the robot's interference, the prosthetic group was capable of performing smooth, straight reaching movements toward multiple targets within a predefined peak velocity range. During early learning in the curl field, the rate of error reduction was no different between groups. However, during late learning, the prosthetic group exhibited significantly greater error magnitude and variability. Aftereffect errors, an indicator of the quality of the developed internal model, were similar among groups as well. Our interpretation of these results is that, while performing rapid, planar reaching movements, the trans-radial UE prosthetic users' ability to adapt to novel environments is largely intact. The following discussion relates our results to the mechanisms of motor adaptation, post-amputation neural plasticity, and motor recovery therapy.

Is the prosthetic device incorporated into the internal model of the arm?

Throughout development the CNS learns to use handheld tools in dynamic tasks, such as using a hammer. Sensory information and practice are critical to the development of the internal models of the arm and the tool needed to perform these tasks. While it is possible that amputees can use similar learning processes to incorporate the prosthesis into the internal model of the arm, several factors might make this process difficult. While adults are clearly adept at learning the dynamics of new tools, there is little evidence that the adult CNS can easily relearn an internal model of an arm which has been altered so dramatically, such as with the loss of the forearm and hand. The prosthesis itself can be considered a tool that interfaces with the stump instead of a hand. However, the stump is not specialized for such a task and provides far less cutaneous sensory input than a hand. For example, the density of cutaneous mechanoreceptors in the fingertips is 20 times larger than in the arm (Weinstein 1968). Thus, the quality of cutaneous sensory information from the stump may not be adequate to develop models of the prosthesis. However, there were no group differences in the null field, early learning or aftereffect size, suggesting that these sensory losses do not play a large role in adaptation, or that amputees effectively compensated for their sensory losses by relying on other modalities such as vision.

Another factor which may hinder integration of the prosthetic limb is limited usage. In unilateral amputees, usage of the amputated arm decreases immediately as the uninjured arm is now used for all tasks that can be done with one arm. The amount of practice required to relearn new models of the residual arm and prosthesis may be much greater than what amputees typically receive. In the acute stages, attempting to move the arm using poor internal models may contribute to user rejection of the prosthesis. A similar phenomenon, called "learned non-use" is believed to occur in the acute stages of stroke (Dromerick et al. 2006).

The mass and moment of inertia of the prosthesis were only 49 and 39% of a normal human limb, yet the kinematics in the null field were no different between groups. One possible interpretation of this result is that the amputees have incorporated the altered inertial properties of the prosthetic device into the internal model of the arm. In order to perform straight, rapid reaching motions, the CNS must excite the appropriate muscles in a feedforward fashion to produce the desired motion and also counter interaction torques about adjacent joints (Gribble and Ostry 1999). This requires the brain to account for the inertial properties of the arm, and to accurately predict the necessary forces for a specific task. In a previous study of rapid shoulder–elbow reaching movements, alteration of the inertial properties of the forearm by addition of a 1.2 kg mass resulted in dramatically misdirected movements with large peak errors (Sainburg et al. 1999). The movements of the amputees in the null field were not misdirected, suggesting they had adapted to the prosthetic arm. The lack of kinematic abnormalities in the null field also suggests that amputees have adapted to the altered muscle power and geometry at the elbow after the amputation (Meimoun et al. 2000). Incorporation of below-knee prostheses into the internal model of the leg have also been reported (Hill et al. 1999).

Late learning abnormalities

There was increased error variability in late learning in the prosthetic users. Increased variability is present in many

neurologically-based motor disabilities (Sanger 2006; Cirstea and Levin 2000; Verbessem et al. 2002; McNaughton et al. 2004; Adamovich et al. 2001) and likely represents an impairment of the CNS that negatively affects ability to use the arm effectively in everyday activities in these populations. Cortical reorganization after amputation is well documented and may have been a cause of the increased variability if one considers that reorganization after amputation is an abnormality of the CNS. There have also been reports of increased motor variability as a result of neck–shoulder pain (Madeleine et al. 2007), and after extended periods of unweighting or bedrest in the lower limbs (Clark et al. 2007; Yoshitake et al. 2007). Increased variability in terms of force fluctuations are also observed in the elderly, and can be partially ameliorated with increased activity levels (Enoka et al. 2003). Therefore, decreased arm use after amputation is another possible explanation for the increased variability in late learning.

There was also increased error magnitude in late learning in the amputees. There is substantial evidence that kinematic error drives motor adaptation in curl field environments (Shadmehr and Brashers-Krug 1997; Scheidt 2000; Milner and Hinder 2006; Burdet et al. 2004). Increased error in late learning in the prosthetic group may represent a decreased sensitivity to kinematic errors during late learning. It is noteworthy that the errors in late learning were significantly larger than during baseline movements in the null field (142% larger in the prosthetic group). One explanation is that below a certain error level, the CNS stops adapting and errors no longer decrease. This level of "acceptable" error appears to be higher in the prosthetic users, perhaps a consequence of decreased arm usage. Interestingly, the two bilateral amputees had the smallest late learning errors, presumably because they were forced to use the limb in everyday activities much more than the unilateral amputees.

Possible effects of usage history

Amputees who were higher functioning with the prosthetic arm, as determined by the Nine Hole Peg Test, also tended to have smaller aftereffects. We expected the opposite result, that higher functioning subjects would be capable of more complete internal models of the force field, and have correspondingly larger aftereffects. One possible explanation relates to the type of activities performed by the prosthetic limbs. Independent of whether the amputated arm was the dominant or nondominant limb before injury, it is clear that the prosthetic arm is used predominantly as a nondominant limb in everyday tasks, such as stabilizing a jar while the uninjured limb opens the lid. We have shown previously that smaller aftereffects are present in the nondominant limb compared with the dominant limb in neurologically normal subjects (Schabowsky et al. 2007). Furthermore, the higher functioning subjects reported using their prosthetic limb more often than lower functioning subjects. Thus, it is possible the higher functioning prosthetic limbs were used most often, and behaved as nondominant limbs in terms of aftereffect size, because the history of usage consisted entirely of nondominant limb tasks. Pre-injury dominant limbs that were rarely used after amputation, performed poorly on the Nine Hole Peg Test, and continued to behave as dominant limbs after amputation in terms of aftereffect size. Recent evidence has shown that limb dominance effects motor performance, with the dominant limb being more effective at feedforward dynamic tasks while the nondominant limb is more suited for performing static positioning tasks (Wang and Sainburg 2007; Duff and Sainburg 2007). Results of this study suggest some of these differences can be reversed with usage history.

Neural plasticity following amputation and its implications on motor adaptation

Motor adaptation requires an accurate model of the arm dynamics and the external environment. The neural contributors of this model are distributed throughout the brain and motor adaptation studies have shown that disruption of specific cortical regions compromises different aspects of the motor learning process. One study indicated that disruption of the primary motor cortex (M1) by transcranial magnetic stimulation (TMS) between the null field experiment and the adaptation experiment compromised consolidation, the transition of short term memory into a long term state (Richardson et al. 2006). Another study investigated the role of the posterior parietal cortex (PPC) during motor learning (Della-Maggiore et al. 2004). This experiment demonstrated that the PPC is responsible for online (after movement initiation) corrections and that disruption of the PPC via TMS caused a late learning phase of significantly larger error. Another group investigated the role of the cerebellum during adaptation and found that it played a key role in updating the internal model while adapting to a novel environment (Smith and Shadmehr 2005). These studies show that a number of cortical and sub-cortical structures play crucial, but different, roles during adaptation and that disrupting participating regions can compromise many aspects of motor adaptation. Such evidence would lead one to predict that neural reorganization following amputation may lead to deficits in motor adaptation.

Cortical reorganization following upper limb amputation and its association with phantom limb pain has been extensively studied (for a review, see Flor et al. 2006);

however, its implications to motor control and prosthetic device training are also important. Imaging studies have found evidence that phantom limb pain is correlated with the invasion of adjacent cortical regions into the motor and somatosensory domains of deafferented limbs (Karl et al. 2001; Irlbacher et al. 2002). Whereas nonpainful phantom limb phenomena was represented by more distributed reorganization in posterior parietal cortex with increased activity in the SI and decreased activity in SII (Flor et al. 2000).

Based on this review of previous work, it is clear that several brain areas important for adaptation undergo reorganization after amputation. Although our experimental paradigm does not allow direct conclusions on the effects of cortical reorganization on performance of our task, it is interesting that the prosthetic subjects' exhibited larger late learning error magnitude and variability. During a similar task, TMS disruption of the posterior parietal cortex of normal participants resulted in larger late learning errors (Della-Maggiore et al. 2004) and phantom limb studies have shown cortical reorganization in the posterior parietal cortex (Flor et al. 2000) for many upper extremity amputees. This correlation implies that cortical reorganization following amputation may have implications on motor control of the prosthetic limb in this task.

Therapeutic implications and the potential for novel prosthetic device training protocols

The current focus in UEA healthcare is the development of improved surgical techniques, pain management and prosthetic technology (Esquenazi 2004; Pasquina et al. 2006); but there is very little emphasis on prosthetic training. Studies have shown that although a majority of UEA patients rely on their prostheses for both personal and professional activities (Millstein et al. 1986; Wright et al. 1995), about one third complain of inadequate number of therapy visits (McCarthy et al. 1998). A decade long statewide survey showed a policy shift toward increasingly shorter acute care hospital stays and lower rates of discharge to inpatient rehabilitation with 60% of amputee patients discharged directly home (Dillingham et al. 1998). A subsequent survey showed that the length of inpatient rehabilitation significantly enhanced the ability of patients with amputation to function in their daily activities, increased vitality, and reduced residual limb pain (Pezzin et al. 2000). Such studies imply that prosthetic training following UEA is largely beneficial, both functionally and personally, and may further increase acceptance of prosthetic devices. Unfortunately, there are no substantial studies investigating optimal prosthetic training techniques.

Two promising training methods for recovery of motor function following brain injury are constraint-induced therapy (CIT) and robot-assisted rehabilitation. Both CIT (Wolf et al. 2006; Wu et al 2007) and robotic therapy (Lum et al. 2002; Hidler et al. 2005; Krebs et al. 2002) have shown encouraging therapeutic potential, and both rely on task-specific repetitive training. Although much of this work has focused on the stroke population (Dromerick et al. 2006; Lum et al. 2006), the concept of providing task-specific, repetitive exercises to enhance function and discourage maladaptive "learned disuse" may be successfully applied to the prosthetic user population. Further research is required to develop optimal prosthetic device training protocols.

The mechanism which may underlie task-specific, repetitive ADL training is motor learning. Our experiment shows that motor adaptation, a form of motor learning, is preserved in trans-radial prosthetic users during a simplified planar reaching task. While control of the shoulder and elbow does play an important role in ADLs, we acknowledge that control of the terminal device is the limiting factor in this amputee population. Therefore, we do not advocate motor therapy using this paradigm, but instead see it as a means of testing for learning impairments that might limit the effectiveness of task-specific, repetitive ADL training. The goal of this first study was to evaluate learning ability in a well-established paradigm that involved control of the intact joints of the prosthetic arm. Future studies will evaluate adaptation ability during grasping tasks using prosthetic grippers.

Conclusion

The UE amputee community faces daunting challenges and many obstacles that hinder functional use of a prosthetic device. Our results demonstrate that prosthetic users maintain the ability to acquire motor skill and adapt to environmental perturbations. We suggest that developing and enhancing internal models for performance of multiple functional tasks via repetitive task specific training may yield improved motor recovery for prosthetic users.

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PROSTHETICS/ORTHOTICS/DEVICES

Effect of Training on Upper-Extremity Prosthetic Performance and Motor Learning: A Single-Case Study

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ABSTRACT. Dromerick AW, Schabowsky CN, Holley RJ, Monroe B, Markotic A, Lum P. Effect of training on upper-extremity prosthetic performance and motor learning: a single-case study. Arch Phys Med Rehabil 2008;89:1199-204.

Objectives: To examine the impact of a new prosthesis on an experienced and highly motivated prosthetic limb user, to evaluate the effects of training and the ability of clinical measures to detect change, and to gain insight into the mechanisms by which improvement occurs.

Design: A single-case study.

Setting: An outpatient clinic.

Participant: A bilateral high-arm amputee (right shoulder disarticulation, left above elbow).

Interventions: Provision of new prosthesis and occupational therapy.

Main Outcome Measures: Action Research Arm Test, box and block test of manual dexterity, Jebsen-Taylor Hand Function Test, and speed and accuracy of reaching movements with and without visual guidance.

Results: In this experienced prosthesis user, provision of a new prosthesis led to an immediate worsening in functional limitation. With training, the subject recovered his baseline status and then exceeded it in both proximal and distal function. All study clinical measures detected change, but the change detected varied as much as 300-fold depending on the measure chosen. The clinical improvements were associated with modest improvements in the speed of reaching but not the accuracy of reaching under visual guidance. Improvements in reaching accuracy without visual guidance were seen after 10 trials, suggesting that some motor learning had occurred.

Conclusions: Provision of a new prosthesis can cause functional decline even in an experienced user; this decline can be reversed with training. There is wide variability in sensitivity to change among functional limitation measures. Although some training-related improvements may have been due to increased speed and accuracy of reaching without visual guidance, skill in prosthesis use also plays a role.

Key Words: Amputation; Arm; Clinical trials; Occupational therapy; Rehabilitation.

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UPPER-EXTREMITY (UE) amputation is an uncommon condition that has received new attention because of a new cohort of amputees resulting from recent military actions and because of its utility in studying aspects of neuroplasticity. Much effort has been directed toward the development of improved prosthetic limb technology, control mechanisms that include direct central nervous system interfaces,[1] and even tissue engineered limbs; these approaches hold great promise.

In contrast, clinical research in UE prosthesis training has lagged. Few if any systematically collected data regarding the effectiveness of prosthetic limb training are available; most training techniques are based on expert recommendation and clinical judgment.[2] There are survey data suggesting that training is associated with better prosthesis use,[3] but a substantial randomized controlled trial of prosthetics or prosthetic limb training techniques has yet to be performed. Despite willingness to pay the high cost of prosthetic limbs, many payers do not support training in the use of these complex body-worn tools and do not require training as part of arm amputee care. McCarthy et al[4] found that one third of patients who had suffered a UE injury including amputation reported lack of an adequate number of therapy visits, but no such data are available specifically for arm amputees. In a large survey[5] of UE and lower-extremity amputees, merely 25% of those surveyed indicated receiving rehabilitation services in the past year. Close to 20% of the respondents reported an inability to access care when needed, with cost cited as the most common limitation.[5]

We undertook a single-case study of UE prosthetic limb training to explore several issues regarding UE prosthetic limb training. First, in an experienced prosthesis user, could provision of a new prosthesis with a different control mechanism cause a measurable decline in performance? Second, could training lead to measurable improvements in prosthetic limb performance, and how well would currently published UE functional limitation measures detect change? Finally, if prosthetic limb performance improved, was it associated with improvements in raw speed and accuracy or from improvements in some other aspect of prosthesis use such as proprioception or the strategy used to accomplish the task?

METHODS

This study was approved by the local human studies committee.

Participant

The subject was a 15-year-old boy referred for prosthetic reevaluation. Three years prior, he had sustained a right shoulder disarticulation and a left proximal one third transhumeral amputation from an electrical injury. He had no medical history and was right-hand dominant before the injury. There were

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healed scars from burns of the residual limbs and part of the upper chest, in addition to scars from the surgical amputations. The subject reported decreased sensation directly over the scar tissue but denied phantom sensation. Cognitive testing performed at school showed no abnormalities.

The patient's previous prosthesis was a joined right passive shoulder disarticulation prosthesis and a left hybrid switch-controlled externally powered transhumeral prosthesis. The shoulder disarticulation side consisted of a passive hand, friction wrist, passive elbow, and passive shoulder. The left side consisted of a body-powered elbow (through left glenohumeral flexion), passive wrist, switch-controlled hand (through left humeral abduction), and chin nudge control for elbow lock and/or unlock. The prosthesis was limited by the patient's inability to don and doff it independently, the overall weight, difficulty with positioning the terminal device, and the inability of the device to separate glenohumeral flexion from humeral abduction, which caused the hand to open while performing reaching movements. The subject reported having moderate difficulties with the previous prosthesis at school with self-feeding of finger foods; he reported being unable to use utensils during self-feeding. Further, he reported using a cuff on his residual left limb to assist with brushing teeth and writing. He also stated he uses his feet to operate his computer, play video games, and manage the remote control for his television.

Study Measures

Jebsen-Taylor Hand Function Test. The Jebsen-Taylor Hand Function Test (JTHFT)[6] is a standardized assessment that measures the amount of time needed to perform 7 hand-based tasks. The tasks vary according to the degree of complexity. Subtests include writing, simulated page turning, lifting small common objects, simulated feeding, stacking checkers, lifting large light objects, and lifting large heavy objects. We administered the JTHFT with the subject standing in front of a table 76.2cm (30in) high.

Action Research Arm Test. The Action Research Arm Test (ARAT)[7] is an impairment level measurement tool that assesses the functional impairments of the UEs. The assessment incorporates 19 items that are divided into 4 subscales: grasp, grip, pinch, and gross movement. The ARAT uses ordinal scoring for each subtest item: 0 describes no movement, and a score of 3 signifies normal movement. Item scores are summed to form a subtest score and then a full-scale score. A maximum score of 57 represents normal movement.

Box and block test of manual dexterity. The box and block test of manual dexterity (Sammons Preston)[a] evaluates a person's ability to transfer 2.54-cm (1-in) blocks from 1 side of a partition to the other within 1 minute.[8] In this case, the participant performed the test while standing.

After demonstration, the patient was allowed to practice for 15 seconds and then began testing.

Procedures

Prosthetic intervention. After a multidisciplinary evaluation, we chose to primarily address the transhumeral amputation on the left. A hybrid device was chosen; this device consisted of a body-powered elbow controlled through glenohumeral flexion combined with a myoelectrically controlled electric wrist and hand. This strategy provided control of the terminal device that was independent from the body-powered elbow as well as proper positioning of the terminal device for functional activities. A traditional above-elbow, figure-of-8 suspension was used to ease donning, and a donning sleeve allowed consistent tissue elongation for proper electromyographic control. The patient was unable to use a traditional elbow lock cable, so a chin nudge control was used to lock and unlock the elbow. The only usable muscle signal was the medial biceps; using a 4-channel processor (Otto Bock 13E195),[b] this biceps signal was used to control an electric wrist rotator (Otto Bock 10S17)[b] and transcarpal hand (Otto Bock 8E44 transcarpal hand DMC plus).[b]

Prosthetic limb training and collection of clinical measures. The patient underwent evaluation in a specialty outpatient therapy setting as part of the baseline multidisciplinary evaluation and after fitting of a new diagnostic prosthesis. All evaluations were performed by the treating occupational therapist, and testing occurred in the same order at each time point. An initial evaluation with the prior prosthesis was performed at day 0, designated as t0. Time 1 (t1) was the evaluation on the first fitting of the new prosthesis, performed on day 7. Evaluation on t1 was performed before any training on the new device. During the next 8 weeks, the subject underwent 13 sessions of prosthesis training, totaling 19.25 hours of therapy in the clinic. Training included proximal strengthening, prosthesis training drills, neuromuscular re-education using MyoBoy,[a] and therapeutic activities focused on problem solving and learning adaptive techniques. Therapy avoided the tasks specifically tested on the clinical measures. Clinical measures were obtained approximately midway (t2 [11.25h of therapy]) through training and at completion (t3).

Objective evaluation of prosthetic limb performance. To supplement the clinical measures with a more quantitative evaluation of prosthesis performance, we studied reaching movements using a planar, 2 degrees-of-freedom robot.[c] The goal of this instrumented evaluation was to measure reaching speed, accuracy, and the role of visual guidance in using the prosthetic limb. Tasks for these purposes have been developed for the able-bodied and for persons with stroke and other neurologic disorders,[9-12] and these tasks were adapted to the capabilities of the prosthetic arm. The motors of the robot were controlled by custom programs[d] that minimized resistance to movement; an inverse dynamics algorithm partially compensated for the inertia of the robot links. As an added safety measure, light-emitting diode sensors[e] were positioned about the perimeter of the workspace. If the handle of the robot moved outside of the designated workspace, the sensors would trigger an emergency stop and turn off the motors.

The patient sat in an adjustable chair, held onto the handle of the robot, and executed reaching movements within a horizontal plane. During the reaching tasks, full-trunk motion was allowed because he used substantial trunk motion as a compensatory mechanism. A splint supported the prosthetic forearm and restricted wrist rotation. The experimental task required the patient to perform reaching movements alternating between 2 start positions toward a single target position under 2 conditions, with and without visual guidance, with the elbow locked. The 2 start positions were positioned 15cm radial to a target that was oriented along the subject's midline. The ipsilateral start position and contralateral start position were positioned at 45° and 135° relative to the mediolateral axis (fig 1). The patient was instructed to perform rapid, ballistic reaching movements to the target. Feedback was provided to encourage the subject to perform reaching tasks with consistent peak tangential velocities. After a trial, the target circle changed color: white signaled that the reaching movement fell within the desired peak tangential velocity range (.35–.45m/s); green and red signaled that movements were too slow or fast, respectively.

Throughout the vision condition, handle position and the desired targets were displayed (real time) as colored 1-cm

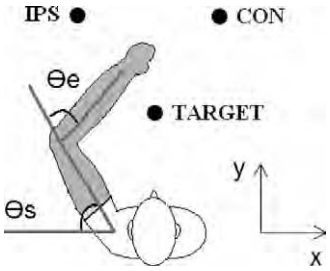

Fig 1. Schematic of the robotic manipulandum experimental task design. The subject's hand started at 1 of the alternating start positions (ipsilateral [IPS], contralateral [CON]) and he performed reaching movements toward the target.

circles on a computer monitor. The patient's performed 20 total reaching movements, alternating between the ipsilateral start position and contralateral start position under this condition. During the no-vision condition, the patient's vision of both the tested arm and the monitor handle position was occluded and only the target circle was visible. After completing a reaching movement, the monitor handle position became visible, providing accuracy feedback. The patient performed 40 total reaching movements under this condition.

Data Analysis

Results of each clinical evaluation are presented. The percentages of change presented in table 1 were calculated by subtracting the score at the later time point from the earlier time point and dividing by the score at the earlier time point. The kinematic data were evaluated across sessions using *t* tests of means. Two comparisons were performed: (1) testing with the old prosthesis versus the first test session with the new prosthesis (t0 vs t1); and (2) the first and last test session with the new prosthesis (t1 vs t3). A Bonferroni adjustment factor of 2 was applied for multiple comparisons. Dependent variables were peak tangential velocity, endpoint error magnitude, and endpoint variability. For each reach, the endpoint location was defined as the point where the tangential velocity dropped below 5% of the peak velocity. Endpoint error magnitude was defined as the distance between the endpoint location and the target. Endpoint variability was calculated as the average of the (Euclidean) distance between each trial's endpoint position and the mean endpoint position for all the trials to a specific target. Endpoint variability is an estimate of the size of the distribution of endpoint positions about the intended target.

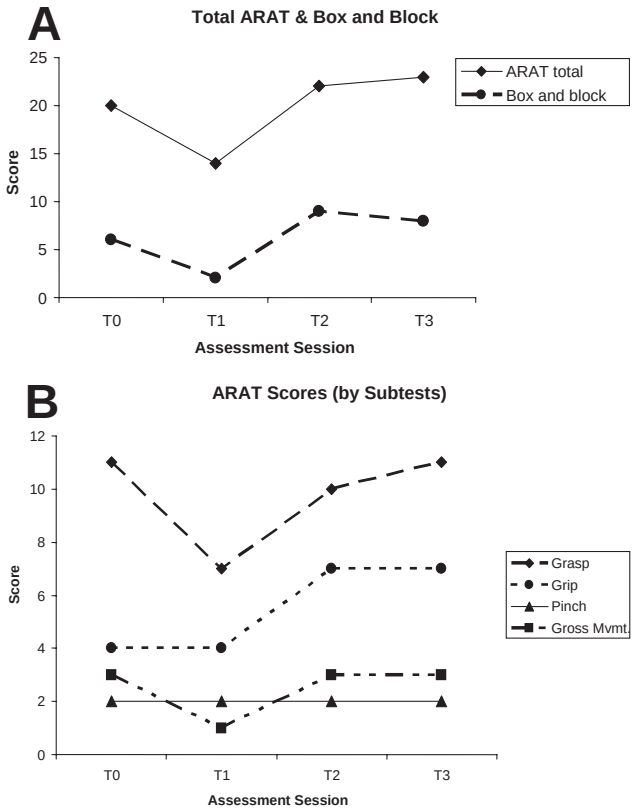

Fig 2. (A) ARAT total and box and block test scores. (B) ARAT subscale scores. Time points: t0, old prosthesis; t1, new prosthesis, pretraining; t2, new prosthesis, 11 hours training; t3, new prosthesis, 19 hours training. Abbreviation: Mvmt, movement.

RESULTS

Clinical Evaluations

The results of the clinical evaluations are presented in figure 2 and tables 1 and 2. Each displays performance at the pretest with the prior prosthesis (t0), with the new prosthesis on initial presentation and before training (t1), approximately midway through training (t2), and at completion of training (t3).

At the pretest time point (t0), tested with the prior prosthesis, the subject was able to accomplish at least portions of most assessment tasks on the box and block test and the ARAT. However, testing with the JTHFT showed substantial difficul-

Table 1: JTHFT Scores

Item	Pretest, Old Prosthesis (t0)	Baseline, New Prosthesis (t1)*	11 Hours Training (t2)	19 Hours Training (t3)
Writing	71	78	102	60
Page turning	87	Unable	189	99
Lifting large light objects	51	106	41	14
Lifting large heavy objects	52	45	30	17
Lifting small objects	Unable	232	424	207
Simulated feeding	Unable	32	20	16
Stacking checkers	Unable	156	175	154

NOTE. Values are in seconds.
*Before prosthesis training.

Table 2: Percentage Improvement as Determined With Different Clinical Measures

Measure	t1 vs t0 (%)	t2 vs t1	t3 vs t2	t3 vs t1
ARAT total	−43	57	5	64
Box and block test	−67	350	−11	300
JTHFT				
Writing	−10	−31	40	23
Page turning	NA	NA	48	NA
Large light objects	−108	61	66	87
Large heavy objects	Became able	33	44	62
Small objects	Became able	−82	51	11
Feeding	Became able	38	20	50
Checkers	Became able	−12	12	1

NOTE. Values are percentage change.
Abbreviation: NA, not applicable.

ties, with 3 of 7 tasks not possible and the rest requiring at least 50 seconds to complete. Thus, with the old prosthesis, the subject was substantially disabled.

The baseline evaluation (t1) occurred on the day of fitting of the new prosthesis, before any training. Compared with the pretest evaluation, performance was worse on most clinical measures. The exceptions were items where performance was near the measurement floor and did not decline further, such as the ARAT grip and pinch subscales, and some tasks on the JTHFT that were impossible with the prior prosthesis but became possible with the new prosthesis. These data indicate that an experienced UE prosthesis user can suffer an overall decline in performance when presented with a new prosthesis.

The next time point (t2) was collected 28 days after fitting; during this period the patient participated in 11.25 hours of occupational therapy (OT). Thus, differences between t3 and t2 represent the summation of improved technical capacity of the new prosthesis, spontaneous learning by an experienced prosthesis user, and formal OT training. Scores on the total ARAT and the box and block test were improved compared with both t1 (baseline with new prosthesis) and t0 (prior prosthesis). Inspection of the ARAT subscale scores (see fig 2) shows that most improvement occurred in grasp and gross movement, a small amount in grip, and none in pinch. Results of the JTHFT evaluation were more mixed, in that there were clear improvements in the more proximal and gross motor performance (lifting large light and heavy objects, simulated feeding) but a decline in more distal and fine motor tasks. Our clinical impression was that the decline may have been related to difficulties in learning the most effective ways to use the myoelectrically controlled wrist and hand.

The final time point was t3, occurring 45 days after fitting, and the subject had participated in a further 8 hours of therapy, bringing the total formal therapy time to 19.25 hours. Any improvements between t2 and t3 are likely to have resulted primarily from training, because by t2, the subject had been exposed to the new prosthesis for several weeks, allowing ample time for self-directed learning. There were no large differences in performance as measured by the ARAT total or the box and block test. However, the JTHFT detected substantial improvements in all 7 tasks, including those in which performance had not declined between t2 and t1.

Table 1 presents the percentage of change detected by each clinical measure, compared across the time points. Inspection shows that in 3 of 4 comparisons there was simultaneous improvement in some measures and worsening in others. In the comparison that evaluated the total effect of the intervention, t3 versus t1, the percentage change varied by 300-fold.

Robotic Manipulandum

The subject was able to achieve the targets with visual guidance, and accuracy did not vary across sessions. Peak speeds for evaluations t0, t1, and t3 were 14.2 ± 0.8, 19.1 ± 0.5, and 22.2 ± 0.7cm/s, respectively. These speed gains between sessions were significant (t0 vs t1: $P<.01$ for both movements; t1 vs t3: $P<.03$ for ipsilateral start position; $P<.1$ for contralateral start position). In the no-vision condition, speed gains were only apparent when starting from the ipsilateral start position; peak speed increased from 17.5 ± 0.8 to 22.4 ± 0.7cm/s between t1 and t3 ($P<.001$).

In the condition where visual guidance was removed, the kinematic errors increased and the subject rarely achieved the target until it reappeared on the visual display. Inspection of the data showed that endpoint errors decreased over the course of the 20 trials in each direction. This would be expected because knowledge of results in terms of endpoint error was provided after each trial. Therefore, we analyzed error magnitude and variability in the first 10 trials separately from the second 10 trials. No changes in error magnitude or variability were found across sessions when analyzing the first 10 reaching movements in each direction. However, there were significant performance improvements during the training period (t1 vs t3) when analyzing the second 10 trials in each movement direction (fig 3). In both directions, error magnitude was reduced ($P<.05$). When starting from the contralateral direction, error variability was reduced with training ($P<.02$).

DISCUSSION

There are case reports in the literature regarding high bilateral amputees and the clinical interventions performed on them.[13-15] These reported improvements in function but were qualitative, did not use kinematic assessments, and did not examine the mechanisms that led to improvement.

We found that presentation of a new prosthesis caused an immediate decline in function as measured using clinical scales, even in an experienced prosthesis user without an intact limb to compensate. There were no associated declines in speed and accuracy under visual guidance as measured with the kinematic measures. This result suggests that the clinical deterioration had more to do with other factors, presumably skill in using a new tool. Although this study design cannot determine how much self-trained function could have been gained in the absence of therapy, it does support the need for some type of prosthesis training, even in experienced users. The magnitude and type of prosthesis changes that should trigger formal training remains to be experimentally determined. The indications for formal training might also vary by patient character-

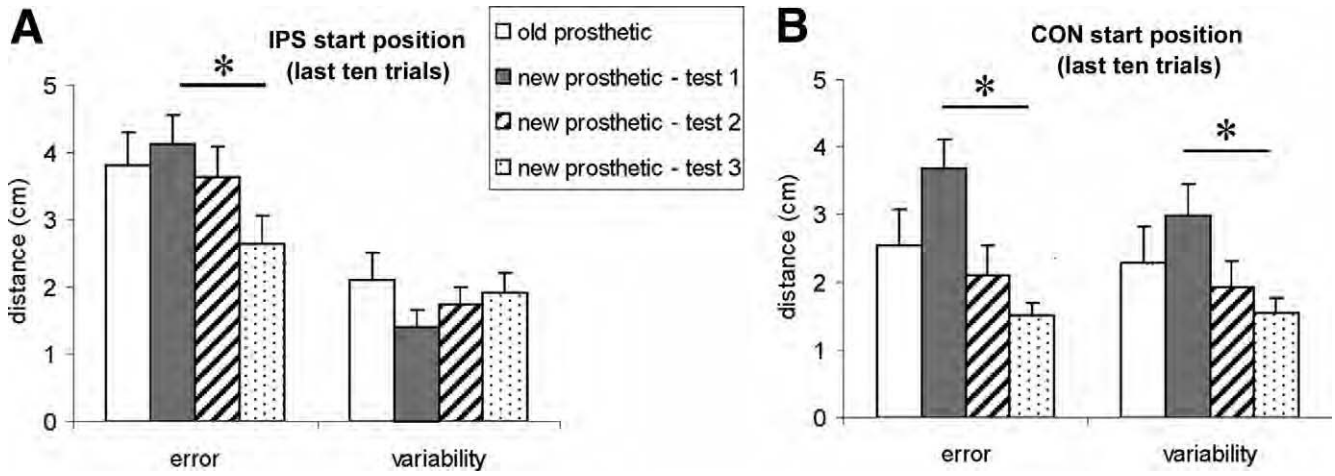

Fig 3. (A), (B) The subject's performance improved between tests 1 and 3 (training period) when considering the last 20 trials in each session. Significant differences between test sessions were determined with *t* tests of means, with a Bonferroni adjustment for multiple comparisons. **P*<.05.

istics, including concordance of hand dominance, cognitive impairments, or age. However, combining this preliminary finding with the well-known learning curve for skill acquisition in a new task,[16] it seems to us hard to justify denial of training when a substantially new prosthesis is provided.

Training led to improvement in clinical performance within a month, and further training led to even more gains in prosthesis performance. These later gains (t3 vs t2) were both proximal and distal, as measured with the JTHFT. The kinematic evaluation provided insights into the mechanisms underlying changes in the clinical evaluations in that speed gains during the training period were apparent; these may have contributed to the improvements in the clinical scales. In the first 10 movement trials in the no-vision condition, the subject did not improve his performance across sessions, suggesting that improvements in the clinical scales were not related to more effective use of proprioceptive input. However, the subject appeared to use error feedback more effectively in later sessions, which may reflect improved motor learning processes as a result of the training.

Study Limitations

Our results also provide preliminary evidence for the utility of UE measures developed in other disabling conditions and show that the apparent response to treatment varied widely depending on which measure was chosen. Developing better training methods will eventually require clinical trials, and valid measures with known psychometric properties are a key aspect of trial methods.[17] In this study, we chose the box and block test because it is the most commonly used measure in the UE amputee literature, allowing comparison with other studies and with clinicians' own experiences. We selected the other measures from another much more common cause of moderate to severe UE dysfunction, stroke. Our results suggest that the use of these more well-known and more psychometrically developed measures is feasible in amputees and that they are able to detect change. We were surprised by the wide variability of clinical change in the functional limitation measures often used in UE assessments, confirming the need for further studies with larger sample sizes. As in stroke, investigators will face the challenge of determining to what extent any improvement in functional limitation leads to improvements in everyday use.[18]

CONCLUSIONS

In an experienced and highly motivated UE amputee, fitting of a new prosthesis was associated with an immediate decline in functional limitation as measured with several clinical scales, despite improved speed of movement of the affected limb. Training was associated with improved functional limitation and speed of movement, but accuracy of movement was not changed. Testing of movement of the affected limb without visual guidance showed no evidence of improvement with training during early trials, but later trials did show evidence of learning. There was wide variation of the apparent response to treatment depending on which time point was evaluated and which measure was used. Further studies will require larger sample sizes, more objectively specified treatment protocols, and clinical measures with known psychometric properties in UE amputees.

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Suppliers

a. Sammons Preston, PO Box 5071, Bolingbrook, IL 60440.
b. Otto Bock Health Care, Two Carlson Pkwy N, Ste 100, Minneapolis, MN 55447.
c. InMotion^2; Interactive Motion Technologies, 37 Spinelli Pl, Cambridge, MA 02138.
d. Matlab 7.1, XPCtarget 2.8; The MathWorks Inc, 3 Apple Dr, Natick, MA 01760.
e. World Beam Q12 series; Banner Engineering Corp, 9714 Tenth Ave N, Minneapolis, MN 55441.